California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GRAY DAVIS, GOVERNOR

Licensing Committee Report

Clarence Hiura, Chair
Don Gubbins, Jr., Member
John Tilley, Member

Report of June 24, 2003

FOR ACTION

RECOMMENDATION 1

That the Board of Pharmacy approve the request from the Community Health Accreditation Program (CHAP) that pharmacies accredited by CHAP are exempt from licensure pursuant to Business and Professions Code section 4127.1(d).

Discussion
Business and Professions Code section 4127.1(d) requires pharmacies that compound sterile injectable drug products to obtain a special pharmacy license from the board. In order to obtain such a license, the pharmacy must first be inspected by the board and found in compliance with board standards for sterile compounding. The bill exempts pharmacies that are accredited by the Joint Commission on the Accreditation of Healthcare Organizations or other accreditation agencies approved by the board from the license requirements. At the last meeting, the board approved Accreditation Commission on Healthcare (ACHC) as an accreditation agency. Exempted pharmacies still must comply with board regulations regarding sterile injectable compounding, but do not have to obtain a separate license.

At the Licensing Committee meeting, Supervising Inspector Dennis Ming reported that he had inspected a CHAP accredited pharmacy and found it to be in compliance. Based on discussion with representatives from CHAP, the Licensing Committee recommended approval contingent on a second inspection of a CHAP accredited pharmacy and submission of additional paperwork that compares the standards between CHAP and JCAHO. **(Attachment A)**

RECOMMENDATION 2

That the Board of Pharmacy support a specialized "clinic" permit for the UC Davis Veterinary Medical Teaching Hospital (VMTH).

Discussion
The VMTH is an academic veterinary clinical training facility as well as a very large, complex veterinary practice. The standard of practice in Veterinary Medicine, as described in the Veterinary Practice Act, is the provision of drugs to a client by the veterinarian, through their practice, subsequent to a veterinarian-client-patient relationship being established.

By 1988, the VMTH had evolved into a very diverse and complex practice. It was also apparent that the centralized pharmacy function was recognized to be extremely important relative to (1) consistency of pharmaceutical practice, (2) having the most current pharmaceutical information available to its clients (by way of the veterinarians), (3) improving the students' education relative to the most current pharmacy practice and regulations, and (4) having the ability to order the appropriate drugs for such a complex practice quickly and efficiently. These factors led VMTH management to the conclusion that the pharmacy activity could best be managed under licensure through the Board of Pharmacy, rather than under the auspices of the individual veterinarians and Veterinary Practice Act.

At that time, the board determined that the closest fit for licensure was a drug room permit. This is a permit that is issued to hospitals that have less than 100 beds. Subsequent to an inspection last year, it was determined by the board that this permit was not the appropriate licensure, and the only option was for licensure as a community pharmacy, which does not fit the needs of the VMTH. The other issue is that VMTH uses many human drugs that are not available through veterinary drug wholesalers and human drug wholesalers are making business decisions not to sell the drugs to VMTH even though pharmacy law does not preclude them from doing so.

Various options were discussed. An option was suggested that a "specialized" clinic permit be designed that would require a consultant pharmacist oversight. It would allow for a common stock and provide a means for the VMTH to obtain a DEA permit. This option would require legislation.

RECOMMENDATION 3

That the Board of Pharmacy submit comments to the ACPE regarding its requirements for registration as a pharmacy technician and the ability for pharmacy technician "trainees" to obtain practical experience in a pharmacy.

Discussion
ACPE has initiated a profession-wide dialog concerning the possible development of national standards and an accreditation process for pharmacy technician education and training. ACPE is the national agency for the accreditation of professional degree programs in pharmacy and providers of continuing pharmaceutical education.

The decision on whether or not to proceed with the development of national standards will be decided at ACPE's meeting in January 2004. If the decision is to establish a national standard, then ACPE anticipates that the process, from initiation to implementation will take about three years.

ACPE has invited organizations and individuals to submit written comments by October 31, 2003, that would be considered during its discussion. It was suggested that the board submit written comment to advise ACPE of California's education and training requirements for

registration and the "pharmacy technician trainee" designee that allows practical training for the technician. **(Attachment B)**

No Action

Implementation of the Licensure and Inspection Program for Pharmacies that Compound Injectable Sterile Drug Products

A pharmacy that compounds injectable sterile drug products that is not accredited by the JCAHO or ACHC must by licensed by the Board of Pharmacy by July 1, 2003. For the prior four months, board staff have been implementing this program. Application forms have been developed, programming for licensing records performed, training of staff provided in processing applications and conducting inspections and information sessions with the profession conducted.

Applications are on the board's Web site for downloading. A self-assessment form has been developed so that pharmacies can review what elements inspectors will check during inspections. There have been a number of questions asked of diverse board staff regarding compliance and the process. The board has also sent a letter to all state boards of pharmacy, advising them of California's requirements. It was suggested to send this information to the already licensed nonresident pharmacies.

To assure that the board inspects all sites possible before July 1, all inspectors have been assigned these inspections as a priority assignment. It was reported that as of June 23, 2003, the board had received 103 applications.

Of the 103 applications, inspectors completed 76 inspections (75%) with the remainder to be completed before June 27, 2003. Of the 76 inspections completed, 59 pharmacy sites (78%) have been approved for licensure and are compliance with CCR section 1751 (including 4 non-resident applications). Nineteen out of 76 applications (25%) were placed on hold pending corrections to come into compliance with CCR 1751. Four (4) applications were found to be accredited by JCAHO and their applications were withdrawn.

Summary of inspector activities and highlights:

- All inspectors completed a one-day training session on conducting sterile compounding inspections.
- The supervising inspector for the program completed inspection assignments with each inspector to monitor uniformity and consistency in conducting the sterile compounding inspections.
- All inspectors have been assigned sterile compounding inspections throughout the state and these inspections were made a priority.
- Inspectors have been provided a standard format for preparing sterile compounding inspection reports.

- A compliance/non-compliance checklist was developed based upon CCR 1751 and used by inspectors to evaluate the pharmacies compliance with the regulation and is available on the board's web site for the licensee's own self assessment.
- A FAQ section on sterile compounding was developed and is on the board's web site.
- Applications for the sterile compounding license have been statewide as far north as Eureka and south to San Diego.
- Northern California applications have centered in the Bay area and Sacramento.
- Southern California applications have centered primarily in Los Angeles and Orange counties with a few in Riverside and San Diego.
- Approximately 10 pharmacies have purchased a commercially available policy and procedure for sterile compounding. These versions have been found unacceptable due to the generic characteristic of the manual. Pharmacies who have submitted "canned" policies and procedures have been contacted with suggestions for revision to make the document specific for their operation. The author of the manual was contacted and advised of the issues.
- The following areas of partial or non-compliance discovered during the sterile compounding inspections have resulted in withholding the issuance of sterile compounding licenses until corrections have been documented: incomplete policies and procedure manuals, lack or incomplete cleaning logs, lack or incomplete equipment calibration logs (pumps, balances, sterilizers, incubators, refrigerators etc), lack or incomplete personnel training/competency documentation, lack or incomplete patient records (some items are difficult for community pharmacies to obtain), presence of porous ceiling tiles over the preparation area (regulation requires non-porous ceiling tiles), lack or incomplete process validation documentation, and lack or incomplete end-product testing for sterility and quantitative analysis. One pharmacy was found to use expired drugs to compound injectable medications (a violation was issued).
- Follow-up telephone calls were made to the PIC one week after the inspection to remind them to submit the requested information. The licensees have been receptive to the corrections and guidance provided during and after the inspections. The pharmacies have complied in a timely manner with providing the requested documents and/or revisions, which has resulted in a relative high number of approved applications for sterile compounding licenses.

It is anticipated that the board will receive a large number of applications during the last week of June. It will not be possible to inspect all of the late applications prior to July 1st and will require a sustained effort by the inspectors after this time period to complete the inspection portion of the licensing process.

The board staff specifically Supervising Inspector Dennis Ming and the inspectors have taken extraordinary efforts to ensure that pharmacies are licensed by July 1, so that patient care is not interrupted.

As determined by the board at its October 2002 meeting, the existing regulations for compounding parenterals is the standard the board is enforcing with respect to licensure. Meanwhile, the board is promulgating additional regulations to deal with requirements for

compounding injectables from nonsterile ingredients. At the April 2003 meeting, changes to this regulation were adopted and released for 15 days of comment. The responses were due June 19th. These new requirements will take effect in January 2005, if the regulation is approved.

Report from the Ad Hoc Committee on Pharmaceutical Benefit Managers (PBM) Regulation – Discussion of Recommendations

At the January meeting, the board created the Ad Hoc Committee on Pharmaceutical Benefit Managers (PBMs) Regulation. This committee is comprised of the board's public members and is functioning under the auspices of the Licensing Committee. The first meeting was held March 4, 2003, and the second meeting June 4th. Board member Dave Fong facilitated both meetings and both were well attended. The meeting on June 4th, focused on the development of a formulary, prescription drug coverage, the P&T Committee process and the role of costs in establishing formularies.

The committee determined that it would discuss recommendations as to the regulation of PBMs at the July Board meeting. To guide the board in this discussion, sample questions from a "Sunrise Questionnaire" that is used by the Department of Consumer Affairs and Senate Business and Professions Committee is provided. This questionnaire is designed to assist proponents of new state boards or new categories of licensed professionals to collect and organize information that is necessary for an objective evaluation. The questionnaire is required pursuant to Government Code Sections 9148.4 and 9148.10. **(Attachment C)**

The Sunrise Questionnaire is typically used for proposed licensure of a new occupational or professional group. The questionnaire is intended to determine the merits of the governmental regulation and the demonstrated need that licensure and regulation is necessary to protect the public. The questions in the following areas should guide the board in making its decision regarding regulation.

- Unregulated practice of this occupation will harm or endanger the public health safety and welfare
- Existing protections available to the consumer are insufficient
- No alternatives to regulation will adequately protect the public
- Regulation will mitigate existing problems

Meeting Summary of June 24, 2003 (Attachment D)

Application/Licensing Statistics (Attachment E)

Competency Committee Report (Attachment F)

The pharmacist licensure examination was given June 17th and 18th, at the San Jose Convention center. It was the largest examination ever. Over 1,300 applicants took the exam.

Final Report on Committee Goals for 2002/03 (Attachment G)

Attachment A

California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GRAY DAVIS, GOVERNOR

July 8, 2003

Patricia Harris
Executive Officer
California State Board of Pharmacy

RE: Community Health Accreditation Program Inc. (CHAP)

Introduction:

The Community Health Accreditation Program (CHAP) is an independent evaluating body for home and community health care organizations. It has been accrediting home care organizations since 1965. In 1987, CHAP became a fully independent subsidiary of the National League for Nursing. CHAP is committed to ensuring that home and community health care providers adhere to the highest standards of excellence, and those standards are maintained through specific guidance for self-improvement.

CHAP currently accredits organizations throughout the United States, Hawaii, and Puerto Rico. There are currently 35 accredited pharmacies located in 14 states.

In California, CHAP has accredited the following pharmacies:

Since November 2001:
Homecare Preferred Choice, Inc, dba Beverly Home Care Infusion Services, Monrovia
Homecare Preferred Choice, Inc, dba Beverly Home Care Infusion Services, Loma Linda

Since October, 2002
Children's Home Care, Glendale

A CHAP introduction document was obtained that described the organization goals and objectives and accreditation process (Exhibit I).

On June 20, 2003, a Board of Pharmacy inspection was conducted at a CHAP accredited facility, Children's Home Care Pharmacy located within Children's Hospital of Los Angeles. This facility specialized in providing intravenous solutions and injections for pediatric patients discharged from the acute care hospital.

Purpose:

The purpose of the inspection was to determine if CHAP pharmacy standards were a viable option to Joint Commission Accreditation of Healthcare Organizations (JCAHO) and to the Accreditation Commission on Healthcare (ACHC) standards for the purpose of compliance with

Business and Professions Code Section 4127.1, subdivision (d): *Pharmacies operated by entities that are licensed by either the board or the State Department of Health Services and that have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board, are exempt from the requirement to obtain a license pursuant to this section.*

Findings:

A. Standards Review

A crosswalk matrix comparing JCAHO and ACHC standards with CHAP standards was obtained (exhibit 2). The following standards were reviewed for comparable standards between the three agencies: Organization and Administration, Program Service Operations, Fiscal Management, Personnel Management, Client Service/Care Management, Quality Outcomes Management, Risk Management: Infection Control and Safety, Clinical Respiratory Services, Home Medical Equipment Services, Rehabilitation Technology Supplier Services, Fitter Services and Pharmacy Services (pages 18, 19 & 20, exhibit 2).

As with JCAHO and ACHC standards, many of the CHAP standards regarding medication use were also inter-woven into the other major categories to demonstrate a continuity of services throughout the organization.

- Describe scope of pharmacy services (JCAHO LD.10, ACHC 838A, **CHAP DII.4)**
- Pharmacy Services were compliant with pharmacy law and regulations (JCAHO HR.3.1, TX.3, LD.5, ACHC 838A**, CHAP CI2a, DI2a, DI.2b, DII4d, DII4, DII5c**)
- Training and education of staff preparing pharmaceuticals were documented (JCAHO hr.3.1, HR.4, ACHC 846, **CHAP DI.3b, DI3c, DIII 1, DIII1a, DIII1d, DIII1c**)
- Describe the preparation and compounding of medications (JCAHO TX.5.1, ACHC 846, **CHAP DII4e, DIII4i, DIII7, DIII7a, DIII3, DIII3a, DIII3d**)
- Personnel were qualified to prepare and compound medications (JCAHO HR.3.1, HR.4, ACHC 846A, **CHAP DIII1b, DIII1d, DIII1e**)
- Describe the compounding environment and procedures (JCAHO TX.5.1, ACHC 846B, **CHAP DIII3e, DIII3f, DIII3g**)
- A written plan for drug compounding was present (JCAHO TX.5.1, ACHC 846C, **CHAP DII7)**
- Cleaning and disinfecting procedures were present (JCAHO EC.3.1, ACHC 846D, **CHAP DIII3a, DIII3d, DIII3g, DII7, DII4)**
- A process to identify, monitor and report adverse drug reactions was present JCAHO TX.6.5, ACHC 844C, **CHAP DII4b, DII6, DII6a**)
- A process to recall medications was present (JCAHO TX.5.4, ACHC 845 A,B, **CHAP DII7b1)**
- A process to educate the client (external and internal) based on the plan of care was present (JCHAO PF.1, PF.1.1, PF.2. PF .3, PF.3.1, PF .3.2, PF.3.4, PF.3.5, PF.3.6, ACHC 842F, **CHAP DII7b3, DII7c, DII1a**)

B. Pharmacy Standards Workbook

Prior to a scheduled survey, CHAP provides the facility with a series of workbook to be used as a self-assessment of operations relative to CHAP standards. The workbooks cover three major areas of operations: the CORE Standards, Infusion Standards, and Pharmacy Standards. Analysis of the pharmacy workbook showed a detailed methodology to determine compliance with CHAP standards. The pharmacy director completes the workbook and is provided an opportunity to come into compliance prior to the survey. The workbooks are returned to CHAPs and reviewed by a surveyor. This information, in conjunction with direct observation during the site survey process, is used by the surveyor to generate a report.

C. Survey Report

A blank CHAP Survey Report was obtained (exhibit 3). The report is divided into the following sections: Organizational Strengths, Organizational Challenges, Organization Summary, Commendations (exceeded the requirements), Required Action (non-compliance with immediate correction), Previously Cited Required Action Now Met, Previously Cited Required Actions Not Met, and Recommendations.

A copy of the CHAP survey report for Children's Home Care Pharmacy was obtained (exhibit 4). On page 13 and 14 of 14, there were two recommendations for Children's Home Care Pharmacy operations: identification of strategies and monitoring parameters to improve the quality of service (process improvement), and separation of clean supplies from the storage areas.

During the board inspection of Children's Home Care Pharmacy, the workbook was reviewed with the pharmacy director and compared to California Code of Regulations Section 1751. Several observations were made and corrections ordered to bring the pharmacy into full compliance with CCR 1751. Specifically, the requirement for non-porous ceiling tiles over the sterile compounding area, documentation of calibration of equipment such as IV pumps, documentation of cleaning processes, and documentation of pharmacist verification of pharmacy technician work on compounding worksheets. These corrections were brought into compliance by the pharmacy director on June 27, 2003, and a sterile compounding license was subsequently issued.

D. Board of Pharmacy Compliance Factors for Accreditation Agencies:

In compliance with Board of Pharmacy requirements for consideration as an alternative accreditation agency, CHAP submitted a response to each required factor. The results are summarized as follows:

- Periodic Inspections: CHAP conducts a full comprehensive site visit to pharmacies at least once every three years.
- Documented Accreditation Standards: Three sets of standards are used to survey a site: CORE Standards, Infusion Standards and Pharmacy Standards. CHAP standards

have been recognized by JCAHO as being comparable in definition and expectations (exhibit 5).

- Evaluation of Surveyor's Qualifications: CHAP requires pharmacy surveyors to have the following minimum qualifications: registration as a licensed pharmacist, 5 years experience in pharmacy management, current experience in community-based or infusion-based compounding pharmacy services, demonstration of strong analytical, consultative, conflict resolution, mediation and written/verbal articulation skills, demonstration of experience with an accreditation process, and successful completion of a CHAP Site Visitor training program and four practicum site visits.
- Acceptance by Major California Payors: CHAP is accepted by all California payors as well as all national payors with the exception of one payor in Southwestern Pennsylvania.
- Unannounced Inspections of California Accredited Sites: An unannounced inspection was conducted by a board inspector of a CHAP accredited site and found to be in compliance and a sterile compounding license was issued.
- Board Access to Accreditor's Report on Individual Pharmacies: A copy of the CHAP survey report was made available to the board inspector.
- Length of Time the Accrediting Organization has been operating: CHAP has been operational since 1965.
- Ability to Accredit Out-of-State Pharmacies: CHAP currently accredits organizations throughout the United States, Hawaii, and Puerto Rico (35 in 14 states).

Summary:

The CHAP pharmacy standards were reviewed found comparable to JCAHO and ACHC standards. CHAP appears to be in compliance with the factors required by the Board of Pharmacy for consideration as an alternative accreditation agency. Review of policies and procedures at the Children's Home Care Pharmacy/CHAP accredited site, were found complete and in compliance with California regulations. JCAHO has recognized CHAP's standards as comparable in definition and expectations/outcome.

During a meeting of the Board of Pharmacy Licensing Committee on June 24, 2003, representatives from CHAP were provided a copy of the board's Sterile Compounding Checklist developed from the California Code of Regulations Section 1751 on Parenteral Therapy for informational purposes. It is recommended that each accreditation agency approved by the board, be provided copies of the checklist as a reference to ensure compliance of the pharmacies accredited by the respective agency relative to California regulations on sterile compounding.

Submitted by:

Dennis L. Ming, Pharm.D.
Supervising Inspector
California State Board of Pharmacy

CHAP
COMMUNITY HEALTH ACCREDITATION PROGRAM

39 Broadway Suite 710 New York, NY 10006 tel: 212-480-8828 fax: 212-480-8832 web: www.chapinc.org

June 5, 2003

Patricia Harris
Executive Officer
California State Board of Pharmacy
400 R Street, Suite 4070
Sacramento, CA 95814

RE: Application for Board Approval under Senate Bill 293, Section 4127.1d

Dear Ms. Harris:

The Community Health Accreditation Program, Inc. (CHAP) is applying to California State Board of Pharmacy for approval to exempt pharmacies from licensure under requirements established by Senate Bill 293, Section 4127.1d of the Business and Professional Code.

Included is CHAP's response to the evaluation factors identified by the Licensing Committee as required in section 4127.1. CHAP supportive documentation is attached as Appendix I – III.

CHAP is a national non-profit accreditation organization established in 1965 as the first organization in the United States to accredit community-based health care organizations. CHAP currently accredits pharmacies in California as well as other States across the Country.

If possible, I request that the Board consider CHAP's application for approval at the July, 2003, Board of Pharmacy meeting.

Please contact me if you need further documentation.

Thank you for consideration of this application.

Sincerely yours,

Terry A. Duncombe, RN, MSHA
President & CEO

APPLICATION TO THE CALIFORNIA STATE BOARD OF PHARMACY FOR APPROVAL TO EXEMPT PHARMACIES FROM LICENSURE UNDER REQUIREMENT ESTABLISHED BY SENATE BILL 293 (SECTION 4127.1D OF THE BUSINESS AND PROFESSIONS CODE)

SUBMITTED BY:
COMMUNITY HEALTH ACCREDITATION PROGRAM, INC. (CHAP)
39 BROADWAY, SUITE 710
NEW YORK, NY 10006
JUNE 5, 2003

Factor 1. Periodic Inspection

The Community Health Accreditation Program, Inc. (CHAP) conducts a full comprehensive site visit to pharmacies at least once every three years. Every standard for Core, Pharmacy, and Infusion Therapy is assessed during these site visits. Based upon the performance of the pharmacy and the findings, particularly in the Quality Standards (Section II of each set of standards), the CHAP Board of Review may determine to require a return site visit within 6, 12, or 24 months to focus on and assess compliance with the required actions cited during the site visit. The Accreditation Process is described in the document, Introduction to CHAP Accreditation, which is included as Appendix I.

Factor 2. Documented Accreditation Standards

CHAP accredits compounding pharmacies. CHAP currently uses three sets of standards to assess pharmacies: Core (overall administrative standards), Pharmacy (service specific standards) and Infusion Therapy (limited to Infusion Pharmacies). The Standards are included as Appendix II. Each of the three sets of standards contain language further requiring compliance with State and Federal statues governing pharmaceutical practice. Each pharmacy is assessed during a site visit for compliance with CHAP standards as well as federal and state-specific regulations. In addition, CHAP standards are consistent with the professional standards of practice as defined by the American Society of Health System Pharmacy and published in Best Practices for Health-System Pharmacy, ASHP, 2002-2003 Edition, and referenced for assessment.

CHAP assesses standards in terms of "Met" or "Not Met." The standard must be met in full to be assessed as "Met." If any element of the standard is not met, the standard is assessed as "Not Met," and a "Required Action" is written for that Standard. Required Actions are actions which the organization is required to perform in order to achieve compliance with CHAP Standards. The Board of Review decision to accredit, deny accreditation or defer accreditation is based upon the number and types of Required Actions identified. CHAP does not use a scoring methodology for assessing compliance and determining accreditation decisions

An organization is **accredited** if the site survey findings provide evidence that the organization Is in substantial compliance with CHAP standards. An organization is **deferred** in initial accreditation based upon evidence that the organization is not in substantial compliance with

the CHAP Standards but has evidence that they possess the ability to come into substantial compliance within a reasonable time frame, not to exceed one year from the deferral date. A full site visit will subsequently be conducted to determine compliance with CHAP standards. An organization is **denied** initial accreditation based upon evidence that the organization is not in substantial compliance with the CHAP Standards and lacks adequate structure and function to correct the deficiencies in a timely manner. The organization has the option of re-initiating the application process six months from the date of the initial site visit. Other Board of Review accreditation decisions include **formal warning** and **termination** which are delineated in the Introduction to CHAP Accreditation, Appendix II.

Factor 3. Evaluation of Surveyor's Qualifications.

CHAP requires pharmacy site visitors to have the following minimum qualifications:

1. Currently licensed Registered Pharmacist with a minimum Bachelor of science in pharmacy.
2. Five years experience in pharmacy management.
3. Current experience in community-based or infusion-based compounding pharmacy services.
4. Demonstration of strong analytical, consultative, conflict resolution, mediation and written and written and verbal articulation skills.
5.. Demonstration of experience with an accreditation process.
6. Successful completion of a CHAP Site Visitor Training Program and four practicum site visits.

CHAP currently has six pharmacy site visitors with professional pharmacy experience ranging from 5 – 40 years, with clinical management experience ranging from 5 – 23 years, with two holding Master degrees and one working on a Doctor of Pharmacy degree. Each one of CHAP's pharmacists is currently employed in active pharmacy services.

The CHAP Board of Review (BOR) has a pharmacist appointed by the Board of Directors. That pharmacist has a Doctor of Pharmacy and is responsible for reviewing and assessing Pharmacy Site Visit Reports to assure consistent citation of pharmacy standards. The BOR Pharmacist is also responsible for assessing new or revised standards as part of the BOR and recommending adoption to the Board of Directors.

Factor 4. Acceptance by Major California Payors

CHAP is accepted by all California payors as well as all national payors with the exception of one payor in Southwestern Pennsylvania.

Factor 5. Unannounced Inspection of California Accredited Sites

CHAP understands that the State Board of Pharmacy will conduct unannounced inspections of two or more California accredited pharmacy sites to assess for satisfactory compliance with California law and good professional practice.

Factor 6. Board Access to Accreditor's Report on Individual Pharmacies

CHAP provides a written report to each pharmacy following a site visit and review and determination by the Board of Review. Each of the pharmacies accredited by CHAP has a copy of the written report available on site. In addition, CHAP Core Standard CI.4a. requires an organization to have a written public disclosure policy that provides public disclosure of the accreditation report and other documents.

Factor 7. Length of Time the Accrediting Organization Has Been Operating

CHAP has been accrediting organizations since 1965. CHAP was the first national accreditation organization to accredit community-based health organizations in the United States and was the first organization awarded deeming authority by CMS (formerly HCFA) for home health in 1992 and for hospice in 1999. CHAP Pharmacy Standards are recognized by JCAHO as being comparable in definition and expectations.

Factor 8. Ability to Accredit Out-of-State Pharmacies.

CHAP currently accredits organizations throughout the United States, Hawaii and Puerto Rico and is able to accredit pharmacies regardless of state of operation.

CHAP currently accredits 35 Pharmacies located in 14 states. CHAP has 44 pharmacies that have applied for accreditation and are in the process of contract execution or currently undergoing the self-study process.

Additional Questions:

1. What companies are accredited for Pharmacy by CHAP in California?

Accredited since November, 2001:
Homecare Preferred Choice, Inc. dba Beverly Home Care Infusion Services, Monrovia
Homecare Preferred Choice, Inc. dba Beverly Home Care Infusion Services, Loma Linda

Accredited since October, 2002:
Children's Home Care, Glendale

Applied for Accreditation:
Factor Support Network Pharmacy, Inc., Camarillo
John Davis Company, Sacramento

2. Is CHAP accreditation comparable to JCAHO ?

JCAHO has completed an evaluation of CHAP standards which resulted in their recognition of general comparability between the standards of our two organizations.

3. What is an example of an evaluation sheet and report?

The CHAP Site Visitor Work Book is used for evaluating compliance with the CHAP Standards. A Board of Review Site Visit Report is generated from the commendations, recommendations and required actions cited in the Site Visitor Work Book. The Board of Review reviews the Site Visit Report and completes a Summary Data Collection Tool in order to assure a logical and focused review of Site Visit Reports and to promote consistency in the interpretation of site visit findings by each reviewer. Consistency in the interpretation of site visit findings by the Board of Review drives the decision making process. A sample of the Site Visitor Work Book, the Board of Review Site Visit Report format and the Board of Review Summary Data Collection Tool are included as Appendix III.

INTRODUCTION

Table of Contents

CHAP INTRODUCTION

OVERVIEW AND HISTORY

The **Community Health Accreditation Program, Inc. (CHAP)** is an independent, non-profit accrediting body. It was the **first** accrediting body for community-based health organizations in the United States and was created in 1965 as a joint venture between the American Public Health Association (APHA) and the National League for Nursing (NLN). These organizations brought to fruition the futuristic view that accreditation was the needed mechanism for recognizing excellence in community health practice. In 1988, CHAP became a separately incorporated, non-profit subsidiary of the NLN under the CHAP name. In 2001, it was spun-off by the NLN and became an independent, non-profit corporation.

CHAP was granted "deeming authority" by the Centers for Medicare and Medicaid Services (CMS—formerly HCFA) in 1992 for home health, and in 1999 for hospice. This means that instead of state surveys, CHAP has regulatory authorization to survey agencies providing home health and hospice services, to determine whether they meet the Medicare Conditions of Participation (COPs).

CHAP accreditation is available to organizations providing the following services:

- Home Health
- Hospice
- Home Medical Equipment
- Home Pharmacy
- Infusion Therapy Nursing
- Private Duty Services (includes professional and paraprofessional services)
- Home Care Aide Services (for paraprofessional-only businesses)
- Public Health
- Supplemental Staffing Services
- Community Nursing Centers
- Community Rehab Centers

STANDARDS OF EXCELLENCE

The CHAP accreditation process uses the CHAP ***Standards of Excellence*** which are driven by considerations of management, quality, client outcomes, adequate resources, and long-term viability. The goal is to assist all types of community-based health care organizations to:

- Strengthen internal operations
- Promote continuous quality improvement
- Promote consumer satisfaction

- Promote positive client outcomes
- Meet community health needs in a cost effective and efficient manner
- Maintain the viability of community health practice nationwide
- Assure public trust in community-based services and products

CHAP is committed to assuring that home and community health care organizations adhere to the highest standards of excellence, and that providers maintain compliance with the current standards. The CHAP ***Standards of Excellence*** provide guidance and reality-based criteria for the evaluation of an organization. These criteria are based on four (4) key "Underlying Principles" (UP), which drive each set of the CHAP standards. Following are these principles:

I. The organization's structure and function consistently supports its consumer oriented philosophy, mission, and purpose.
II. The organization consistently provides high-quality services and products.
III. The organization has adequate human, financial, and physical resources to accomplish its stated mission and purpose.
IV. The organization is positioned for long-term viability.

In keeping with its goal of elevating the quality of all community health care in the United States, CHAP continually reviews and updates the ***Standards of Excellence.***

CHAP accreditation publicly certifies that an organization has voluntarily met the highest standards of excellence for home and/or community-based health care. Additional benefits of accreditation by CHAP include management consultation of the highest quality, access to a broad network of professional resources, and guidance critical to building intra and inter-organizational collaboration and strength.

GOVERNANCE

CHAP is governed by an independent, voluntary Board of Directors. Members of the Board of Directors represent consumers, purchasers, and providers, as well as experts in the home and community health care industry. Responsibilities of the Board of Directors include:

- Determining CHAP's philosophy, mission, and purpose
- Establishing its policies and planning for the future direction
- Assuring compliance with statutory and regulatory requirements
- Evaluating CHAP's performance in relation to its philosophy, mission, and purpose

PHILOSOPHY

The CHAP Philosophy assures the availability of quality home and community-based health care through the voluntary commitment to accreditation by the applicant organizations. This is essential as home and community health care become the centerpiece of the health care industry. It is CHAP's firm belief that the

accreditation process should clearly separate excellent organizations and programs from those meeting only minimal standards. CHAP further believes that standards should be:

- Driven by the goal of consumer protection
- Easily understood and administered
- An instructive tool that encourages a participative process for organizations
- Used to evaluate the total system of care, services, and products

Mission

The CHAP Mission is to provide leadership for enhancing the health and well-being of diverse communities. This is achieved through the development of the ***Standards of Excellence*** which assure the management of ethical, humane, and competent care in home and community-based organizations. In addition, the development and dissemination of innovative products, services, and models of care, as well as the creation of partnerships, promote this mission.

Purpose

The CHAP Purpose is to develop and promote standards applicable to all types of home and community-based health service providers. Providers range from individually-owned businesses to large corporations, for-profit and/or non-profit, public and private. To accomplish its purpose, CHAP:

- Provides an external, objective marker for organizations' consumers, demonstrating that they meet national standards of quality
- Provides consumer-oriented national standards for the full range of services and products available
- Conducts evaluations of providers and grants accreditation to those organizations meeting or exceeding CHAP standards
- Promotes the development and dissemination of new knowledge and products by encouraging on-going research
- Provides information to assure that purchasers and consumers have information readily available to make informed decisions

Accreditation Process

Eligibility for Accreditation

All home and community-based health care service providers are eligible to seek accreditation by CHAP. Applicant organizations must meet the following criteria:

- Have legal authority to operate
- Provide one or more of the services or product lines listed on page three
- Prepare and submit the required accreditation application documentation and fees on a timely basis

CHAP will accredit separate and distinct programs or services individually. CHAP recommends, however, that all home and community-based health care programs and services of an organization be included in the accreditation process.

Accreditation Cycle

Organizations are accredited for a three-year cycle. A self-study and full site visit initiate the accreditation cycle. Site visits may be made in years 2 and 3 of the cycle, based upon the on-site findings and the Board of Review determinations.

Fees

Accreditation fees are based on the size and complexity of an organization. An initial, non-refundable application fee is required at the time of the application. CHAP divides the accreditation fee into three annual payments. In addition to the annual fees, there is a charge for the standards and self study. A separate per diem charge is made to cover site visit expenses. The projected number of site visit days is determined according to the size, complexity, and number of locations of the applicant organization. No site visit will take place until the first annual fee payment has been made. Accreditation fees are due and payable in accordance with the following schedule:

- A non-refundable application fee is due with the submission of the application
- The first annual fee and charge for the standards and self-study are due with the submission of the signed contract
- The second and third annual fee payments are due on the anniversary date of the signed contract
- Site visit fees are billed at the completion of the visit and are due within thirty (30) days

At the conclusion of the formal Exit Conference, the lead site visitor completes the *Pre-Billing Report* and obtains the signature of an authorized official of the organization, which certifies the number of on-site days. The lead site visitor faxes the completed form to the CHAP office at the end of the last day on-site. The original is returned to the CHAP office with the *Site Visit Report* documents.

The 4 Steps of the CHAP Process

Step 1 – Application and Contract

The applicant organization completes the CHAP *Application for Accreditation* form and sends it with the application fee to CHAP. Upon receipt of the application, CHAP staff will:

- Determine the organization's eligibility for accreditation
- Establish a fee based on the information from the organization's application
- Estimate the number of site visit days necessary to assess the organization

An organization-specific contract is developed from the information in the comprehensive application. The contract delineates the duties and responsibilities of CHAP and the organization for a three year cycle. It locks in the annual fee and per diem rate for the number of anticipated site visit days. Two original contracts are sent to the organization for review and signature. The appropriate standards and self-study will be sent under separate cover. Both copies of the original signed contracts should be returned to the CHAP office within 30 days. One original contract will be returned to the organization, and one retained in the CHAP office after CHAP's President/CEO has signed them.

Step 2 – Self-Study

The *Self-Study Report* is a unique and insightful self-evaluation tool, which addresses both the business and service aspects of the applicant organization. The *Self-Study Report* is due back in the CHAP office within six months of the date of the signed contract. CHAP staff will review the report and begin analysis of the content. (A one time three-month extension may be granted under qualifying circumstances.)

The purpose of the self-study is two-fold.

- It gives the organization the opportunity to complete a comprehensive internal evaluation in preparation for the site visit.
- CHAP uses the information submitted in planning the site visit process. An updated self-study should be submitted at the start of each accreditation cycle.

Step 3 – Site Visit Process

The site visit team is comprised of health care professionals experienced in their respective fields. The composition of a site visit team is contingent upon the type of visit, size of the organization, and the complexity of services and products provided. The focus is to provide professional assistance while ensuring compliance with the CHAP ***Standards of Excellence*** and other regulatory requirements. Emphasis is placed on the "Underlying Principles."

Site Visitors

"Site Visitor" is the term CHAP uses for those professionals who go on-site to organizations to assess the quality of the services and products provided. Lead site visitors are assigned whenever teams are used to conduct a site visit and have the primary responsibility for the site visit process overall. Lead site visitor qualifications include a minimum of five (5) year's senior management experience in a community-based health care organization and education at the master's level. The lead site visitor is responsible for coordinating all the activities of the site visit team and ensuring the timely completion of the *Site Visit Report*. In addition, the lead site visitor provides consultation to the organization.

Other site visitors are required to have five (5) years experience in a health care field that reflects the scope of care and services accredited by CHAP and have a bachelor's degree in a related specialty area. Nurses must have a BSN. Periodically, CHAP employs the use of "peer site visitors" who are selected from the management staff in other CHAP accredited organizations to participate in on-site activities.

Site visits may be conducted by one site visitor or by a team, based on the size, complexity, type of expertise needed and number of service delivery sites.

Planning and Scheduling Site Visits

CHAP staff is responsible for the planning and scheduling of all site visits. All visits to Medicare home health and hospice organizations will be unannounced if the agency has chosen to use CHAP's deeming authority.

Organizations seeking accreditation, but not using CHAP's deeming authority from Medicare, may elect in writing to have prior knowledge of the date of the scheduled visit.

Organizations not visited on an annual basis will be required to submit annual progress reports or copies of internal annual evaluation reports.

Organizations designated for a return visit no sooner than 36-months, will be assigned to a pool from which 5% of the organizations will be randomly visited.

Types of Site Visits

- **Initial Site Visit -** the first on-site visit made to an organization at the beginning of the accreditation cycle. (Year 1)
- **Annual Site Visit -** Site visits may be required in year 2 or 3 of the accreditation cycle depending on the outcome of the initial site visit (Newly certified Medicare home health agencies must have a site visit every year for three years, per Medicare regulations.)
- **Focus Visit -** site visit made in less than a year to follow-up with critical required actions
- **Complaint Investigation Visit** - site visit made to assess the validity of a complaint, usually related to patient care and safety issues.

Prior to a site visit, the organization completes the *Pre-Site Visit Questionnaire.* The questionnaire will be used to identify any changes made in the organization since the completion of the self-study, and to provide logistical information for site visitors (e.g., hotels, directions, etc.)

The Entrance Conference

The lead site visitor announces the arrival of the CHAP site visit team and requests a meeting with the CEO and designated members of the administrative team. The purpose of this Entrance Conference is to:

- Demonstrate the preparedness of the team to conduct the site visit in a knowledgeable and organized manner
- Facilitate a professional and positive experience for the organization during the site visit
- Explain and plan the site visit activities and time frames

- Inform the organization about the materials, documents, and statistical information needed by the site visit team
- Engage all levels of the staff in the accreditation process
- Explain the consultative component of the site visit
- Establish the time, place and participants for the Exit Conference

At the Entrance Conference the (lead) site visitor will explain the responsibilities of the applicant organization, which include:

- Orienting site visitor(s) to the physical plant
- Introducing site visitor(s) to key staff
- Designating a primary contact person to work closely with the site visitor(s)
- Providing reasonable workspace for the site visit team
- Notifying clients and obtaining verbal permission for the home and service site visits
- Transporting site visitor(s) to home and service site visits
- Providing directions for travel to remote service sites
- Responding in a timely manner to requests from site visitor(s) for accreditation related documents and statistical data
- Arranging for interviews with key personnel and governing body member
- Arranging for observational experiences for site visitors
- Providing copies of video/audio taping of the Exit Conference at the close of the site visit

Client Visits

Site visitors make visits to clients receiving care and services in the home and/or community-based settings. The purpose of these visits is to:

- Verify that the care, services, and products provided by the applicant organization meet CHAP standards
- Validate that the care, services, and products provided are consistent with the organization's policies and professional practice standards
- Assure that direct and contracted care, complies with the clients' plan of care/services
- Determine the clients' satisfaction with the plan of care/services

Selection of Client Visits

On the first day of the site visit, the organization will provide a list of clients scheduled for visits that week. The site visitor will select a random sample of clients to be visited, taking into consideration diagnosis, payer source, service mix, and willingness of clients to allow these visits. For large organizations with multiple service sites, other considerations include travel time, distance, and previously visited sites.

Permission for Client Visits

The organization contacts clients and receives verbal approval for the visit prior to the site visit. The purpose of a client visit is to observe the activities and interview the

client/representative in a non-disruptive manner. The site visitor is responsible for obtaining written approval from the client or client representative using the CHAP *Consent for Home Visit* form for home visiting and/or the CHAP *Consent for Home/On-Site Visit* form for public health site visits. A copy of the signed consent is distributed to the client and the organization. The original is returned to the CHAP office as a part of the *Site Visit Report*.

Telephone Surveys

The site visitor may conduct telephone surveys of discharged clients and major referral sources to determine the level of satisfaction with the services and products provided by the organization. Sub-contractors may be contacted to address the level of compliance with the organization's policies and CHAP standards.

The Exit Conference

The (lead) site visitor conducts an Exit Conference with designated members of the organization's staff. CHAP encourages the participation of management and supervisory staff as well as members of governing boards, advisory committees, and community members. The purpose of the Exit Conference is to:

- Applaud the agency for voluntarily seeking accreditation
- Extend appreciation to the organization for its cooperation with the site visit team
- Verbally report the findings of the site visit as they relate to the CHAP standards
- State the level of compliance with the *Medicare Conditions of Participation* for certified agencies through the CHAP deeming authority
- State the site visit team recommendation to the Board of Review
- Explain the function and accrediting authority of the Board of Review
- Provide an opportunity for the organization to ask questions or respond to the presentation
- Bring closure to the site visit

Consultation

Additional benefits of accreditation by CHAP include: management consultation as part of the site visit, telephone consultation while preparing the self-study, access to a broad network of professional resources, and guidance to building intra- and inter-organizational collaboration and strength. Senior management and the (lead) site visitor will set the consultative agenda prioritizing areas for attention. Consultation will be provided at the conclusion of the Exit Conference.

Step 4 – Determination of Accreditation Status

The *Site Visit Report* is the legal document that states the organization's level of compliance with CHAP standards. The *Centers for Medicare & Medicaid Services* (CMS) forms become a part of the *Site Visit Report* for home care and hospice organizations that have elected to receive Medicare certification through the CHAP deeming authority.

BOARD OF REVIEW

The Board of Review (BOR) is the external body authorized by the CHAP Board of Directors to review and analyze site visit reports and make decisions regarding the accreditation status of applicant organizations. The BOR is comprised of senior management and quality specialists from CHAP accredited organizations, and industry experts. The actions taken by the BOR are based on the *Site Visit Report* from the site visit team that assessed the organization on-site. The determination of the accreditation status, and any follow-up actions required of an organization, is based on the "required actions" and "recommendations" of the site visit team. Careful deliberation of the *Site Visit Report* and review of other documents form the basis of the accreditation decision. Responsibilities of the BOR include:

- Reviewing site visit reports and progress reports
- Analyzing report data for relevance to the CHAP standards with particular emphasis on "commendations" and "required actions"
- Making objective accreditation decisions based on the site visit team recommendations and the results of the BOR analysis
- Documenting BOR findings on the *Board of Review Summary* form for each report reviewed
- Determining time frames for progress reports, focus visits, and next site visit using survey frequency guidelines
- Making recommendations to the Board of Directors and CHAP administration regarding accreditation policies, procedures, and practices
- Maintaining organizational information in a strictly confidential manner

Following the BOR session, CHAP staff complete the internal processing of the reports. Written notification regarding the final accreditation decision will be sent to the organization within 4-6 weeks following the BOR meeting. CHAP retains accreditation reports and related documents for two accreditation cycles or six (6) years. Possible Board of Review determinations include:

- Accreditation
- Accreditation with Required Actions
- Accreditation with Required Actions and a Progress Report Due
- Accreditation with Required Actions, a Progress Report Due, & follow-up Focus Visit
- Defer Accreditation (initial accreditation only)
- Formal Warning (continued accreditation only)
- Deny Accreditation (initial accreditation only)
- Withdrawal of Accreditation (continued accreditation only)

The organization may call the CHAP office to receive its accreditation outcome. The details of the findings and follow-up actions required will be outlined in the letter of notification. Organizations should receive their letter of notification 4 to 6 weeks following the BOR meeting.

RECONSIDERATION

The applicant organization has the right to request a reconsideration of the findings of the BOR. This process begins with verbal notification to the Vice President Accreditation, followed by written documentation from the organization delineating its issues and concerns, within ten (10) working days. The BOR will review and evaluate the request at their next meeting, and issue a written report of their decision and findings.

APPEAL

The applicant organization then has the right to appeal the findings of the BOR to the Appeal Panel, if it is still dissatisfied with the accreditation determination. The process is similar to the request for reconsideration. Again, it begins with verbal notification to the Vice President Accreditation, followed by written documentation from the organization explaining its rationale, within ten (10) working days from the initial call.

The Accreditation Appeal Panel is a committee of the CHAP Board of Directors and, as such, is appointed by the Chair of the Board of Directors. It is comprised of four members of the Board of Directors, at least two of whom have direct home or community-based health care knowledge and management experience, and at least one consumer representative. The presence of at least three members is necessary to conduct a meeting of the Appeal Panel. A vote that indicates agreement among a majority of those in attendance and voting determines a decision. Decisions of the Appeal Panel are final. Responsibilities of the Accreditation Appeal Panel include:

- Reviewing data regarding the appeal, (e.g., *Self-Study Report, Site Visit Report, Board of Review Summary*, and the organization's written documentation of concerns and issues)
- Conferring with appropriate individuals in order to obtain information relative to the appeal (e.g., site visitor, Board of Review member, and/or organization representative)
- Determining whether the decision of the BOR is substantiated by the data submitted
- Ruling to affirm, reverse, or change the document or send back the *Site Visitor Report* to the Board of Review for re-consideration, and specifying in writing the reasons for the ruling.

CHAP Basics

THERESA S. AYER, MS, RN, CNAA

Editor's Note: *As home care and hospice agencies increasingly seek accreditation from the Community Health Accreditation Program (CHAP)— until recently a subsidiary of the National League for Nursing—it is important that* Home Healthcare Nurse *keep our readers aware of various aspects of this program. Starting with this column in our first issue of 2002,* HHN's *Accreditation Strategies column will share timely information about both CHAP and the Joint Commission on Accreditation of Healthcare Organizations (Joint Commission) on an alternating basis. Readers who have specific questions and concerns or a topic they would like discussed in this column on either of these accreditation programs should contact the Editor at chump@homehealth.win.net or via phone: (502) 339-9005.*

History

The Community Health Accreditation Program (CHAP) began accrediting home health agencies in 1965 as a division of the National League for Nursing. In 1987, it became a subsidiary incorporated with the CHAP name. The next evolution occurred in 2001, when in mutual recognition of the diverging goals and missions of the National League for Nursing and CHAP organizations, CHAP was spun-off as a totally separate nonprofit corporation.

Throughout the last 34 years, the CHAP mission has been to provide leadership for the evolving home care community with a focus on the consumer and community needs. CHAP began with a focus on home health, at the same time the new Medicare reimbursement for this service began in 1965. Its initial goal was to assure quality home care as the service shifted from primarily maternal-child health to a focus on the elderly.

Always consumer oriented and driven to focus on the needs of the consumer, consumers have consistently served on CHAP's Board of Directors and Board of Review. In addition, these Boards have included representatives from business, health insurance, and accredited organizations to assure that CHAP Standards and processes stay current and relevant to the types of services being accredited. With this consumer focus, and in recognition of changing and evolving consumer needs, CHAP has added accreditation for many other community-based health services over the years and now accredits community-based organizations providing services in 11 different areas.

Deemed Status

CHAP was the first accrediting body to receive Home Health Deeming Authority from HCFA (now CMS) in 1992, and renewed in 1999 as well as being first to receive Deeming Authority for Hospice also in 1999. "Deeming Authority" means that the federal government assures that CHAP's Standards of Excellence meet or exceed the government's own requirements for Medicare certification. Therefore, CHAP may evaluate home health and hospice organizations under the CMS Conditions of Participation and regulations for both home health and hospice in lieu of state surveyors conducting a survey. Therefore, CMS states that agencies meeting CHAP standards are "deemed" to have met CMS requirements.

CHAP views accreditation as a process and not an event; it focuses on how the agency looked during the last site visit, how it has since evolved and improved, and its plans for future enhancements.

In 1996 the Joint Commission entered into a cooperative accreditation agreement with

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Figure 1. CHAP Accredits Organizations That Provide the Following Services:

- Home Health
- Hospice
- Home Infusion Therapy
- Pharmacy Services
- Home Medical Equipment
- Private Duty
- Public Health Services
- Community Nursing Centers
- Community Rehabilitation Centers
- Home Care Aide Services
- Supplemental Staffing

CHAP. This agreement was "designed to reduce the duplicative onsite evaluations of home care organizations in integrated organizations surveyed under the Joint Commission's Network Accreditation Program" (CHAP, 1996). In reaching this agreement, CHAP's accreditation processes were compared to those of the Joint Commission and were found to be comparable. CHAP and the Joint Commission maintain separate philosophies and approaches to accreditation, but the ultimate goals for each organization (i.e., quality patient care at home) are the same.

The CHAP Accreditation Process

CHAP views accreditation as a process and not an event. Agencies must continually strive to improve their operations and outcomes, aiming for excellence. CHAP accreditation does not view an organization in just a snapshot, but is interested in how the agency:

- looked during the last site visit (survey),
- has since evolved and improved, and
- is planning for future enhancements.

More specifically, it looks for improvement in its systems and outcomes related to all its customers, internal and external. That is, improvements should be aimed at staff, physicians, and other referral services as well as patients.

At any time while working with agencies, CHAP seeks ways to contribute to the refinement of the organization's clinical operations, business practices, and achievement of positive outcomes. Therefore, CHAP is not interested in accrediting home care organizations that have the ability to just scrape through the accreditation process successfully, but rather, those organizations that express an ongoing commitment to quality improvement and positive outcomes.

The Four-Step Accreditation Process

Accreditation by CHAP is accomplished through a simple, four-step process:

1. the application and contract process,
2. agency completion of a self-study,
3. a site visit, and
4. determination of accreditation status by the Board of Review.

Standards

Accreditation standards are revised as needed when changes occur in service areas. In 2001, CHAP revised the Core, Home Health, and Hospice Standards of Excellence. CHAP has separate Standards of Excellence and Self-Studies for each type of service organization (see Figure 1), plus Core Standards of Excellence and Self-Study that are applicable to all types of organizations. All Standards outline the requirements for achieving CHAP accreditation.

For example, an organization with home health, hospice, and home medical equipment (HME) would complete one Core Self-Study for all three services plus the Home Health, Hospice and HME Self-Studies. The Self-Study is a tool an organization can use to guide it through a structured evaluation of its internal capabilities and quality of operations. Because it is an intensive self-examination that requires significant effort and time, CHAP allows 6 months for the completion of the Self-Study. It is a step-by-step guide for the self-assessment of administration, clinical services, and financial operations, and is beneficial to any organization seeking improvement.

Each set of these Standards and Self-Studies is divided into four sections based on four key, underlying principles (see Figure 2). These principles address the structure and function of the home care organization; the quality of its services and products; the adequacy of its human, financial, and physical resources; and its long-term viability. For example, Underlying Principle II (UP II) focuses on quality of services and products in every set of Standards and Self-Study. This section of the Core Standards contains criteria and elements related to:

- organizational policies and procedures;
- client access to care, services, and products;
- prioritization of care delivery;
- planning, implementing, monitoring, and evaluation;
- clinical records;
- total quality management; and
- health and well being of employees and clients (CHAP, 2001a).

This section of the Home Health Standards has a similar albeit more specific focus on home health quality. Specifically, Section II addresses:

- specific services,
- access to care and services,
- care coordination,
- home health-specific policies and procedures (requirements not addressed in the Core Standards),
- CLIA requirements,
- medication management,
- effectiveness of care, and
- telemedicine (CHAP, 2001b).

CHAP prides itself on its consultative approach. While completing an objective organizational review, consultation is provided after the Exit Conference on any area that the organization or site visitors think would be helpful.

The CHAP Site Visit

The Site Visit Workbook used by CHAP visitors while in the agency again follows the same four principles. The lead site visitor, prior to beginning the site visit, reviews the Self-Study to begin understanding how the organization functions. The review of the Self-Study may also identify areas of concern that will receive extra scrutiny during the site visit. The site visitor(s) completes the on-site evaluation following the structured approach of the Underlying Principles.

The site visit includes Entrance and Exit Conferences and a review of various types of organizational records and activities (with a particular focus on clinical records and home visits for all services provided). CHAP prides itself on its consultative approach to this evaluation. While completing a fair and objective review of the organization, consultation is provided after the Exit Conference on any area that the organization or site visitor(s) believes would be helpful.

The site visitors prepare the site visit report that is presented to the CHAP Board of Review (held bimonthly) with recommendations for accreditation, deferring, or withdrawing accreditation. The Board of Review then reviews the findings and makes the final accreditation decision. An appeal process exists for any organization that may disagree with Board findings. There is also a mechanism for more immediate action if the site visitors find serious clinical problems that they feel may jeopardize patients.

Figure 2. CHAP Standards of Excellence: Key "Underlying Principles."

I. The organization's structure and function consistently support its consumer-oriented philosophy, mission, and purpose.

II. The organization consistently provides high-quality services and products.

III. The organization has adequate human, financial, and physical resources to accomplish its stated mission and purpose.

IV. The organization is positioned for long-term viability.

(CHAP, 2001a).

CHAP MISSION STATEMENT

CHAP's mission is to provide leadership in enhancing the health and well being of diverse communities. This mission is achieved by:

- developing standards of excellence that assure the management of ethical, humane, and competent care in home, community, and public health settings;
- developing and disseminating innovative products, services, and models of care;
- creating partnerships; and
- utilizing resources efficiently.

(www.chapinc.org/mission.htm)

Summary

The CHAP accreditation process was established to provide an objective, external process for evaluating an organization's effectiveness in meeting its own mission, while the organization was providing services that meet national care standards. The entire CHAP review process is based on a nursing model of care—that of organizational assessment, strength and weakness identification, appropriate organizational interventions, and evaluation that provides a holistic approach to an organization's performance. CHAP expects to see a home care or hospice organization providing effective services that are appropriate for the patient population and communities it serves.

For more information about the CHAP accreditation process:

Web site: www.chapinc.org

Telephone: (800) 656-3656, ext. 242

Mail: CHAP, 61 Broadway, 33rd Floor, New York, NY 10006

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Show *Home Healthcare Nurse* your creative side!

Have an interesting story about a patient situation you've experienced as a home care nurse? Perhaps you have written a moving poem or thought about how something that happened in your practice would make a humorous cartoon. *Home Healthcare Nurse* would like to share your thoughts and feelings with other readers through poems, cartoons, word puzzles, and serious and amusing anecdotes. We have an illustrator, so don't worry about your artistic abilities. Just send in your ideas and we'll work with you from there. Please make sure that patient confidentiality is assured when writing. We're sure you have something great to share!

Send your contributions to:

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COMMUNITY HEALTH ACCREDITATION PROGRAM, INC.

CROSSWALKS

CHAP/JCAHO/ACHC*

*Crosswalks for CHAP programs are provided for comparison

EXHIBIT 2
OF
PAGES

CHAP/JCAHO/ACHC CROSSWALK
Home Medical Equipment & Pharmacy

Note: Standards are cross-walked according to the intent of the standard and not according to the exact language of the standard. Reference to JCAHO standards are made to standards in the JCAHO manuals for home health services, home care pharmacy services, home medical equipment, respiratory therapy and rehabilitation technology.

DESCRIPTION	CHAP STANDARD	JCAHO STANDARD	ACHC STANDARD
Organization and Administration			
Legal Authority	CI.2a	LD.1	101
Documentation of legal authority	CI.2, CI.2b	LD.1	101 A
Change in authority	CI.2i8	No JCAHO standard	101 B
Governing Body	CI.2c	LD.1, LD.1.1, LD.3, LD.6, LD.6.1	102
Governing body duties	CI.2, CI.2f,h,i. CIV.2d	LD.1.1, LD.2, LD.2.1	102 A
Description of governing body	CI.2, c, d	LD.1, LD.9	102 B
List of governing body members	CI.2d	No JCAHO standard	102 C
Composition of governing body	CI.2	LD.1, LD1.1	102 D
Orientation of governing body	CI.2e	LD1.1	102 E
Professional advisors	CI.2c	No JCAHO standard	103
P&P for professional advisors	HHI.2g	No JCAHO standard	103 A
List of professional advisors	HHI.2e	No JCAHO standard	103 B
Orientation of professional advisors	CIII.1k – applied to PAC	No JCAHO standard	103 C
Conflict of interest	CI.2g	RI.12	104
Written policy for conflict of interest	CI.5b	RI.12	104 A

DESCRIPTION	CHAP STANDARD	JCAHO STANDARD	ACHC STANDARD
Written conflict of interest policy will be shared with staff	CI.2h	No JCAHO standard	104 B
Identification of individual responsible for organization	CI.4, CI.4a, CI.4e, HMEI.4	LD.3, LD.6, LD.6.1, LD.7	105
Designation of individual	CI.4, 4a	LD.7	105 A
Job description for designated individual	CI.4a, CI.4b	LD.7	105 B
Individual is qualified	CI.4a,CI.4b	LD.7	105 C
Periodic written evaluations of designated individual	CIII.1i, CIII.1j, CI.2f	HR.7	105 D
Designation of person in absence of executive	CI.4c	LD.7.1	105 E
Organizational structure	CI.3, CI.3a	LD.9	106
Organizational chart	CI.3a, CI.3b, HME1.3a	LD.9	106 A
Person identified for overall supervision	CI.3a, HMEI.4a	LD.8, HR.3.2	106 B
Organizational chart shows persons responsible	CI.3a, HMEI.3a	LD.9	106 C
Design of organizational chart	CI.3a, CI.3b	LD.9	106 D, E, F
Job descriptions	CIII.1c	HR.2	106 G
Written mission/philosophy statement	CI.1, CI.1a, CI.1b, HMEI.1, HMEI.1a	LD.4	107
Compliance with law and regulation	CI.2a, CI.2i, CI.4d, CI.5h, CII.1c, CII.5a, CII.7a, CIII.1g, CIII.5a,	LD.5	108
Written policies related to compliance with law and regulations	CI.5h, CI.5e, CI.5f, CII.1c, CII.5a, HMEI.5b	LD.5	108 A

DESCRIPTION	CHAP STANDARD	JCAHO STANDARD	ACHC STANDARD
Notification of accrediting body when outcomes from other audits may effect accreditation or licensure		No JCAHO standard	108 B
PROGRAM/SERVICE OPERATIONS			
Description of services available to staff, clients, community	CI.4d, CII.1a, HMEI.1c	RI.1, RI.11	201
Description of services	HMEI.1c	RI.1, RI.11	201 A
Designated staff familiar with services and can respond to inquires	CII.8c	No JCAHO standard	201 B
Description provided to clients	HMEI.1c	RI.1	201 C
Bill of Rights	CII.1b	RI.1.1	202
Informing client of rights	CII.1c, CII.1d	RI.1.1	202 A
Written bill of rights/responsibilities	CII.1b	RI.1.1, PF.3.7	202 B
Staff understand bill of rights	CII.1d	RI.1.1, HR.5	202 C
Client grievance procedure	CII.1b8,9, CII.8, a,b	RI.4	203
Grievance process	CII.1b8, 9, CII.8a, b	RI.4	203 A, B
Staff understand grievance process	CII.8c	RI.4, HR.5	203 C
Confidentiality of client information	CI.5c9, CII.1b6, CII.5a, CII.5e	RI.5	204
Information provided to client about confidentiality	CII.1b, CII.1c	RI.5	204 A
Written policies about confidentiality	CI.5c9, CI.5d7,8	IM.2, IM.2.1	204 B

DESCRIPTION	CHAP STANDARD	JCAHO STANDARD	ACHC STANDARD
Staff, board members knowledgeable about confidentiality	CI.5i, CII.5a	IM.2, HR.5	204 C
Release of information	CI.5h4, CII.5b	IM.2	204 D
Client's right to refuse treatment, advance directives	CI.6c, 10	RI.2.1, RI.2.2	205
Policy for refusal of care, advance directives	CI.6d3	RI.2.1, RI.2.2	205 A
Advance directives and resuscitation	CI.6c10, CI.6d3	RI.2.2	205 B, C
Reporting of abuse/neglect	HHII.7a8	PE.4, PE.4.1	206 A, B
Handling ethical issues	CI.7, a, b, c	RI.10, HR.8	207
Written policy for handling ethical issues	CI.5b3	RI.10	207 A
Accountability and training for ethical practices	Ci.7b	HR.5	207 B
Services for clients of various cultures, religious beliefs	CII.2a	No JCAHO standard	208
Consideration of client's culture, beliefs	CII.2a	RI.1	208 A, B
Communication in various languages or forms	CI.6, a,b	RI.3	208 C
Corporate Compliance Plan	HMEI.6, a, b, c.	RI.11, RI.12, RI.13	209 (PREFERRED STANDARD
FISCAL MANAGEMENT			
Annual budget	CIII.3d	LD.2.2	301, 301 A
Annual review of budget	CIII.3c, CIII.4c1	LD.2.2	301 B
Capital expenditure plan	CIII.3d	LD.2.2	301 C
Written policy for expenditure limits	CIII.3a	No JCAHO standard	301 D

DESCRIPTION	CHAP STANDARD	JCAHO STANDARD	ACHC STANDARD
Fiscal policies	CIII.3a	LD.10	302, 302 A
Accounting system		No JCAHO standard	302 B
Maintenance of finance records, annual audit	CI.5h, CIII.3g, CIII.4, a, b, c,	No JCAHO standard	303 A, B
Established rates for services	CIII.4d, HMEII.2b8	No JCAHO standard	304
Communication of rates for services	CII.1b11, HMEII.2b8,10	RI.2, RI. 11	304 A
Sliding scale rates	CII.1b11, HMEI.6a	No JCAHO standard	304 B
PERSONNEL MANAGEMENT			
Personnel policies	CI.5d	LD.10	401
Specific personnel policies	CI.5d 1-9	LD.10	401 A
Polices accessible to staff	CI.5i, CIII.1f	No JCAHO standard	401 B
Job descriptions, review of job descriptions with staff	CIII.1c, CIII.1k	HR.2	402 A, B
Selecting and hiring	CIII.1a, CIII.1b, HMEIII.1a	HR.3, HR.3.1, HR.3.2	403 A
Reference checks	CIII.1g5	HR.3.1, HR.3.2	403 B
Credentials	CIII.1g2,3,4,7, HMEIII.1a2	HR.3.1, HR.3.2	403 C
Health Screens	CI.5e, CII.7f, HMEIII.1a3	HR.3.1, HR.3.2	404 A, B
Drivers license	HMEIII.1a2	No JCAHO standard	404 C
Criminal background check	CIII.1g16	HR.3.1, HR.3.2	404 D
Personnel files maintained	CI.5d7.8, CI.5h, CIII.1h	HR.3.1, HR.3.2	405 A
Orientation	CIII.ig11, CIII.1k	HR.5	406 A, B, C
Demonstration of competence	CIII.1g8,	HR.4	407
Training, education, skills	CIII.1g13, CIII.1l	HR.4	407 A
Demonstration of competence	CIII.1g8	HR.4, HR.4.1, HR.4.1.1	407 B
Inservice education plan	CIII.1l	HR.6	408 A
Supervision by qualified personnel	HMEIII.1c	HR.3.2	409

DESCRIPTION	CHAP STANDARD	JCAHO STANDARD	ACHC STANDARD
Policies regarding supervision	CI.5d	HR.3.2	409 A
Appropriate supervision available during all hours	HMEIII.1c	HR.3.2	409 B, C
Personnel evaluation	CI.5d9, CIII.1i, CIII.1j	HR.7	410
Annual observation visit of direct service staff	CIII.1g8, CIII.1i3,	No JCAHO standard	410 A
Annual performance appraisals shared with staff	CIII.1i4, CIII.1j	HR.7	410 B, C
Written contracts/agreements	CIII.2,a,b	LD.11	411 A, B, C, D, E
CLIENT SERVICE/CARE MANAGEMENT			
Client record maintained	CII.5, a-g	IM.7	501
Content of client record	CII.5f, HMEII.7, a,b	IM.7	501 A
Signed and dated entries	CII.5d	IM.7.1	501 B
Management of records	CI.5h	IM.2.1	501 C
Policies for referral and intake process	CI.5c1,2,3,5, HMEI.5b2, HME II.1a	CC.1	502
Qualified intake/referral staff adhere to policies	HMEII.1a	CC.1	502 A
Physician license verification	HHIII.2	TX.2.1.1	502 B
Eligibility of clients	HMEI.5b2	CC.1	503
Written eligibility guidelines	CI.5c2,3	CC.1	503 A
Organization only admits patients they can provide services to	HMEII.1a	CC.1	503 B
Written policy for anti-discrimination	CI.5c1	No JCAHO standard	503 C
Written verification that clients meet eligibility requirements	HMEI.5b2	No JCAHO standard	503 D

DESCRIPTION	CHAP STANDARD	JCAHO STANDARD	ACHC STANDARD
Coordination of services with other community agencies	CII.2b	CC2. CC2.1, CC.4, PF.3.6	504 A
Initial and periodic reassessments	HMEII.5a, HMEII.5c	PE.1, PE.2, PE.3	505
Written policies for initial assessments	CI.5c4	PE.1, PE.2, PE.2.1	505 A
Content of initial assessment and reassessments	CI.5c4,	PE.2, TX.8.4, RI.2.4, PE.6, PE.7. PE.8, PE.9, PE.10, PE.11	505 B
Assessments conducted by experienced personnel	CIII.1b, CIII.1c, HMEII.5	PE.1, HR.3.1	505 C
Reassessments	CIII.1c, HMEII.5	PE.3	505 D
Preparation, administration, and delivery of nutritional therapy	HII.4h2	TX.8.1, TX.8.2, TX.8.3, TX.8.5	506 A, B, C
Personnel are designated as case managers for each client	HHII.1bg, HHII.3d,3,4	CC.3.2	507 A
Communication and coordination of care	CII.4, a, CII.2b	CC.2, CC.3	508
Communication among employees	CII.2b	CC.2, CC.3, HR.5.1	508 A
Communication and coordination with other agencies	CII.4, a	CC.4	508 B
QUALITY OUTCOMES IMPROVEMENT			
Quality Improvement activities	CII.6, HMEII.8	LD.12, LD.12.2	601
Implementation of QI activities	CII.6e, CII.6f, CII.6g, HMEII.8a	LD.12, LD.12.2	601 A
Involvement of leadership in QI	CII.6h, CIV.2d, HMEIV.2a	LD.12.1, LD.12.2, LD.12.2.1	601 B

DESCRIPTION	CHAP STANDARD	JCAHO STANDARD	ACHC STANDARD
Staff involvement in QI	CII.6	LD.12.3	601 C
QI includes all aspects of the program and services	CII.6, HMEII.8	PI.2, PI.2.1, PI.2.2, PI.3, PI.3.1, LD.12.2	602
Annual evaluation must be included in QI activities	CIV.2c, HMEIV.2a	LD.4, LD.12.5	602 A
Assessment of at risk processes, sentinel events	CII.7j, CII.7l, CIV.2b	LD.12.4.2, PI.3.1.2	602 B
Client record review	CII.6e, HMEII.8e1,3,4, HMEII.5d	IM.7.3	602 C
Internal Benchmarking: Monitoring of one aspect of care for each program service provided	CII.6d	PI.3.1.1, PI.3.1.2, PI.3.1.3, PI.3.1.4	602 D
Monitoring of one administrative/operational aspect of service	CII.6d	As above	602 E
Client satisfaction	CII.6f	PI.3.1.1	602 F
Data collection methods	HMEII.8a, CII.7l 2	PI.3	603
Criteria for data collection	HMEII.8a7	PI.3	603 A
External benchmarking	CII.6d	PI.4.2	603 B
Annual QI report	HMEIV.2a	LD.12.4.1	603 C
Utilization of information from QI activities	CII.6g, HMEII.8a7	PI.4.4, LD.12.4	604
Written plan of correction in response to unacceptable findings.	CII.6e, CII.6g, CII.7l,3	PI.4.2, PI.4.3, PI.4.4, LD.12.4, LD.12.4.1	604 A
Written summary of outcomes, changes made	CII.6h	LD.12.4.1, PI.5	604 B

DESCRIPTION	CHAP STANDARD	JCAHO STANDARD	ACHC STANDARD
Data are systematically aggregated and analyzed on an ongoing basis and statistical techniques are used to analyze and display data	CII.6h, CII.7l 2	PI.4, PI.4.2	Additional JCAHO Standards
Data analysis and transmission	CII.6e, CII.7l	IM.3, IM.4, IM.5, IM.5.1, IM.6, IM.8, IM.10	Additional JCAHO Standards
RISK MANAGEMENT: INFECTION AND SAFETY CONTROL			
Infection control program	CI.5g, HMEII.9b, c	IC.1, PF.3.9	701
Infection control program consistent with regulatory standards	CII.7a, CII.7c	IC.1, IC.1.3, IC.1.4	701 A
Compliance with OSHA	CII.7a	IC.1	701 B
Staff follow infection control guidelines	CII.7h, CII.7n	PF.3.9	701 C
Effectiveness of infection control program monitored	CII.7d, CII.7e	IC.1, IC.1.1, IC.1.2, IC.1.5	701 D
Safety program	CII.7j, HMEII.9a	EC.1.1, EC.1.1.1, EC.2.1, EC1.5, EC2.5	702
Staff education about safety issues related to service provision.	CII.7g	EC.1.1, HR.5, EC.1.2, EC.2.2	702 A
Home safety assessments and client education	CII.7k, HMEI.5b6, HMEI.5b11, HMEII.2b11, HMEII.2c	EC.1.1, EC.2.1 EC.1.3, EC.2.3, PF.3.3, PF.3.8, PF. 3.12	702 B
Patient/family is educated when appropriate about the use of restraints	CII.1b25	PF.3.13	702 A, B

DESCRIPTION	CHAP STANDARD	JCAHO STANDARD	ACHC STANDARD
Crisis situation – Emergency/ Disaster Planning	CII.3,a,b,c, HMEII.3,a,b	EC.1.4, EC.2.4, PF.310	702 C
Implementation of infection control procedures	CII.6e,f,g, HMEII.8a	IC.2	702 C
The organization plans for and implements a plan for managing utilities.	CII.7j8	EC.1.7, EC.2.7	703 A
Safe and secure environment to include emergency power system.	HMEII.4c1, HMEII.4d1, HMEII.4e1	EC.1.1.2, EC.1.5, EC.1.7.1, EC.2.8.1, EC.2.8.2, EC.2.9.1, EC.2.9.2	704 A
Organization implements its fire safety and management plan.	CII.7e, CII.7j, HMEI.2a6	EC.1.1.2, EC.1.5, EC.1.7.1, EC.2.8.1, EC.2.8.2, EC.2.9.1, EC.2.9.2	704, B
Management of hazardous materials	CII.7e, HMEI.2a4, HMEII.10c	EC.1.3, EC.2.3	705
Polices for management of hazardous materials	CI.5b6,7, CI.5c10,11, HMEII.9a	EC.1.3, EC.2.3	705 A
Compliance with OSHA hazardous communication standard, laws and regulations	CII.7, CII.7a, HMEI.2a3	EC.1.3, EC.2.3, LD. 5	705 B
Hazardous materials, oxygen in the client's home	HMEI.2a, HMEII.10c, 10c1	EC.1.3, EC.2.3, EC.1.6.1, EC.2.9.3, PF.3.8, PF.3.11	705 C
Variance reporting	CII.7l	EC.4.1, EC.4.2	706 A, B
Utilizing data from variance reports	CII.7l	EC.4.3	706 C
Waived tests under CLIA	HHII.5	TX.11, TX.11.1, TX.11.2, TX.11.3, TX.11.4, TX.11.4.1, TX.11.4.2	707 A, B, C

DESCRIPTION	CHAP STANDARD	JCAHO STANDARD	ACHC STANDARD
SCOPE OF SERVICES CLINICAL RESPIRATORY SERVICES		See JCAHO manual for Respiratory Therapy for the following standards	
Clinical Respiratory Care services will be provided by qualified personnel in accordance with policies, law and regulations and standards of practice.	CI.5c12,13, HMEI.2a, HMEI.5b11, HMEII.5	HR.3.1, TX.3, LD.5	850
Clinical respiratory Care services per law and regulation	CI.2a, HMEI.2a2	TX.3, LD.5	850 A
There are written policies for clinical respiratory care	HMEI.5, HMEI.5b11	LD.10	851 A
Clinical respiratory services are available 24/7	CI.5c8	CC.2	851 B
Qualified personnel supervise clinical respiratory services	HMEIII.1c,1,2	HR.3.2	852 A
Clients assessment of need and participation in the plan of care.	CII.1b10, HMEII.5, HMEII.5a	PE.2, RI.2	853
Appropriate assessment of client	HMEII.5a1	PE.2, PE.2.1	853 A
Written plan of care	HMEII.5b, HMEII.5c	TX.1, TX.1.1, TX.1.2, TX.1.3, TX.2	853 B
Client involvement in plan of care documented	CII.1d, HMEII.5b9, HMEII.5c8	RI.2, RI.2.1, CC.3.1	853 C
Client education based on plan of care	HMEII.5a4, HMEII.2c,1	PF.1, PF.1.1, PF.2, PF.3, PF.3.1, PF.3.2, PF.3.4, PF.3.5, PF.3.6	853 D

DESCRIPTION	CHAP STANDARD	JCAHO STANDARD	ACHC STANDARD
Plan of care and services are appropriate for the client	HMEII.5d, HMEII.5a6	TX.1.1	854 A
Respiratory care services are provided in accordance with the plan of care	HMEII.5, HMEII.5a6	TX.1.1, TX.1.2, TX.1.3	854 A
There is consistency between the care provided and the plan of care and services billed	HMEI.6, HMEI.6a, HMEI.6c	TX.1.4, TX.2	854 B
Plan of care is reviewed	HMEII.5a6, HMEII.5d	TX.1.6, TX.4	854 C
Changes are made in the plan of care based on reassessment	HMEII.5a6, HMEII.5d	TX.1.6	854 D
Physician orders obtained as required, physician notification of changes in client condition	CI.5c6, HMEII.2a, HMEII.5b9, HMEII.5c7	TX.2.1, CC.4.1	854 E
Client education based on plan of care	HMEII.5a4	PF.3, PF.3.1	854 F
Transfer and discharge of clients, policies for transfer and discharge	CI.5c3,5	CC.5, CC.5.1, CC.5.2, CC.6, IM.7.2	855 A, B
Administration of pharmaceuticals and treatments	HMEII.4f, HMEII.5a5	TX.3, TX.6	856
Medication administration policies and procedures	HMEII.4f	TX.6	856 A
Respiratory care practitioner assesses client medication	HMEII.4f4,5, HMEII.5a, HMEII.5b6	TX.6.1, TX.6.2, TX.6.3, TX.7,TX.7.1, TX.7.2	856 B
Adverse drug reaction policies	HMEII.4f3	TX.6.5	856 C
Access to library and reference materials	CIII.1I	IM.9, IM.9.1	857 A

DESCRIPTION	CHAP STANDARD	JCAHO STANDARD	ACHC STANDARD
SCOPE OF SERVICES HOME MEDICAL EQUIPMENT SERVICES	See JCAHO manual for pharmacy and/or Home Medical Equipment for the following standards		
Written policies related to home medical equipment program	CI.5c, CI.5e, CI.5f, CI.5g, CI.5h, HMEI.5, HMEI.5a, HMEI.5b	EC. 1.6.1	861
Written policies describing the scope and services offered by the HME service program.	CI.5c, CI.5e, CI.5f, CI.5g, CI.5h, HMEI.5, HMEI.5a, HMEI.5b	LD.10	861 A
Emergency home medical equipment services are available 24 hours, 7 days a week.	HMEII.2d, 1, 2, 3,, HMEII.2e	EC.1.6.4, EC.1.6.4.1, EC.1.6.4.2	861 B
Qualified personnel supervise HME services	CI.4, CI.4b, CI.4d, HME,I4, HMEI.4a, HMEII.1c	HR.3.2	862 A
Client assessment for need	HMEII.4a2	PE.2, PE.2.1	863 A
Client participation in plan of care	CII.Id, HMEII.2b6	RI.2, RI.2.1, CC.3.1	863 C
HME services are goal oriented and delivered in accordance with a physician order when required	CII.5,c, HMEII.2a, HMEII.4,a,b,c,d,e, HMEII.5,a,b,c	TX.1.1 TX.1.4, TX.2	864 A
HME services are directed at achievement of client goals	CII.5,c, HMEII.2b,d,e,f	TX.1.1, TX.1.4	864 A
There is consistency between HME services provided and written plan of care and services billed.	HMEI.6, HMEI.6a, HMEI.6c	TX.1.4, TX.2	864 B

DESCRIPTION	CHAP STANDARD	JCAHO STANDARD	ACHC STANDARD
Transfer and discharge of HME clients, policies for transfer and discharge	CI.5c3,5	CC.5, CC.5.1, CC.5.2, CC.6, IM7.2	865 A, B
[illegible] services are provided consistent with law, regulations, policies	CI.5c, CII.7m, HMEI.2a, HMEI.5, HMEI.5a, HMEI.5b	TX.3, LD.5	866
The organization implements policies for client ready equipment	HMEI.5b3,4,5,6	EC.1.6.1, EC.2.6, EC.2.6.1	866 A
The organization implements policies for set-up and delivery of equipment	HMEI.5b 3,5,6 HMEII.2b1-12 HMEIII.2c	EC.1.6.3	866 B
There are written policies for maintenance and repair of medical equipment	HMEI.5b4, HMEII.2f, HMEII.10a, HMEII.10b, HMEIII.1b, HMEIII.2a, HMEIII.2d	EC.2.9.3	866 C
Procedures for tracking equipment and handling recalls	HMEI.5b8, HMEII.10c	EC.2.6.1.1	866 D
Policies for processing soiled HME are implemented	HMEI.5b10, HMEII.9, a,b,c	EC.2.6.1	866 E
HME staff have access to reference library	CIII.1l	IM.9, IM.9.1	867
SCOPE OF SERVICES REHABILITATION TECHNOLOGY SUPPLIER SERVICES	See JCAHO manual for Rehabilitation Technology services for the following standards		

DESCRIPTION	CHAP STANDARD	JCAHO STANDARD	ACHC STANDARD
Rehabilitation Technology Supplier (RTS) services will be provided by qualified personnal in accordance with policies, Law and regulations and standards of practice.	CI.5c12,13,14, HMEI.2a, HMEI.5, HMEII.2c2, HMEII.6	HR.3.1, TX.3, LD.5	870
RTS services per law and regulation	HMEI.2a, HMEI.5	TX.3, LD.5	870 A
There are written policies for Rehabilitation Technology Supplier Services.	HMEI.5, a,b	LD.10	871 A
Qualified personnel supervise RTS services	HMEIII.1c	HR.3.2	872 A
Client assessment of need	HMEII.6, 6a,6b	PE.2, PE.2.1	873 A
Client participation in plan of care	CII.1b10, HMEII.6a, HMEII.6b	RI.2, RI.2.1, CC.3.1	873 C
RTS services are goal oriented and delivered in accordance with a physician order when required	CI.5c6, CII.5c, HMEII.2a, HMEII.6a1, HMEII.6a2	TX.1.1 TX.1.4, TX.2	874 A
RTS services are directed at achievement of client goals	CII.5c, HMEII. 6a2, 6b, 6c	TX.1.1, TX.1.4	874 A
RTS services are evaluated in relation to established goals	CII.5c, HMEII.6b, 6d	TX.1.1, TX.1.4,TX.4	874 A
There is consistency between RTS services provided and written plan of care and services billed.	HMEI.6, 6a, 6c	TX.1.4, TX.2	874 B

DESCRIPTION	CHAP STANDARD	JCAHO STANDARD	ACHC STANDARD
[illegible] of RTS clients, policies for transfer and discharge	[illegible].5b3,5	[illegible], CC.5.1, CC.5.2, CC.6, IM7.2	875 A,B
[illegible] consistent with law, regulations, policies	[illegible]HMEI.2a, HMEI.3	[illegible]X.3, LD.5	876
[illegible] organization implements policies for client ready equipment	[illegible].5b3,4,5,6, HMEII.6d	EC.1.6.1, EC.2.6, EC.2.6.1	876 A
The organization implements policies for set-up and delivery of equipment	HMEI.5b3,5,6 HMEII.2b1-12 HMEII.2c,2, HMEII.6c, 6d	EC.1.6.3	876 B
There are written policies for maintenance and repair of medical equipment	HMEI.5b4, HMEII.2f, HMEII.10a,b, HMEIII.2a, HMEIII.2b, HMEIII.2d, HMEII.6d, e, f, HMEIII.1b, HMEIII.2e	EC.2.9.3	876 C
Procedures for tracking equipment and handling recalls	HMEII.10d, HMEII.6f	EC.2.6.1.1	876 D
Policies for processing soiled RTS equipment are implemented	HMEI.5b4,10, HMEII.9,a,b,c	EC.2.6.1	876 E
RTS provides quality products and services	HMEII.8,a	No JCAHO standard	877
Provision of on-site RTS services	HMEIII.2b, d, e	PE.2, PF.3.3	877 A
RTS offers a variety of equipment and options	HMEII.6c,1	No JCAHO standard	877 B

DESCRIPTION	CHAP STANDARD	JCAHO STANDARD	ACHC STANDARD
RTS provides products for loan in the case of equipment failure	HMEIII.6e4, HMEIII.2e	No JCAHO standard	877 D
Provision of warranty for products and services	HMEII.6e	No JCAHO standard	877 E
RTS staff have access to reference library	CIII.1l	IM.9, IM.9.1	878 A
SCOPE OF SERVICES FITTER SERVICES Companies that specialize in post-mastectomy care and products			
	Comparable to HME, Clinical Respiratory and Rehabilitation Technology Supplier Services	No JCAHO standards	880- 886
Additional JCAHO Standards			
Functional rehabilitation assessment and care plan development.	HMEII.6b, HMEII.5c,3	TX.12, TX.12.1, TX.12.2, TX.12.3, TX.12.4, TX.12.5	
Pharmacy Services			
Pharmacy services provided consistent with law, regulations and recognized standards of practice and policies	CI.2a, DI.2a, DI.2b, DII.4d	TX.3, LD.5, LD.10.1	835.a
Written policies describe pharmacy services	DII.4	LD.10	836.a

DESCRIPTION	CHAP STANDARD	JCAHO STANDARD	ACHC STANDARD
Pharmacy services are provided according to the plan of care and available 24/7	DII.1.a, DII.2, DII.4a	TX.1.4, TX.2, TX.5, TX.5.6	836.b
Qualified personnel supervise pharmacy services. A pharmacist supervises pharmacy technicians	DI.3, DI.3a, DI.3b, DIII.1e, DIII.1f	TX.3, HR.3.2	837.a,b
Pharmaceutical care is ordered by a physician, and provided in accordance with the plan of care.	CII.4b, DII.1a	TX1.1, TX1.2, TX.1.3, TX.2	838.a
Client assessment for need and participation in plan of care	CII.4, DII.3a, DII.3b, DII.5a	PE.2, RI.2, RI.2.1, CC.3.1	838.b,c
Pharmacy services are directed at client goals	CII.6c, DIV.1a	TX.1.2	838.d
Pharmacy services follow transfer and discharge procedures	CII.4a, CII.4a1	CC.5, CC.5.1, CC.5.2, CC.6, IM.7.2	838.e
Administration of pharmaceuticals and medical treatments is in accordance with applicable laws, regulations and policies	CI.2a, DI.2a, DI.2b, DII.4, DII.4d, DII.5c	TX.6, LD.5, LD.10.1	839.
A licensed pharmacist reviews client medication prior to dispensing	DII.1a	TX.5.2, TX.5.2.1, TX.5.2.2, TX.5.3, TX.6.1, TX.6.2, TX.6.3, TX.7, TX.7.1, TX.7.2	839.a
Written guidelines for training and education of pharmacy staff preparing pharmaceuticals	CIII.1.i, CIII.1i1,CIII.1i2, DIII.1, DIII.1a, DIII.1b, DIII.1c, DIII.1d, DIII.1e	HR.3.1, HR.4, HR.6	839.c

DESCRIPTION	CHAP STANDARD	JCAHO STANDARD	ACHC STANDARD
Adverse drug reaction policies	DII.6, DII.6a, DII.4b	TX.6.5	839.d
Pharmacy records include lot numbers and expiration dates, product formulation	DII.4c, DII.5b, DII.5c	TX.5.3	840.a.b
Preparation and compounding of medications.	DII.4e, DII.4i, DII.7, DII.7a, DIII.3, DIII.3a, DIII.3d	TX.5.1	841
Qualified personnel prepare and compound medications	DIII.1b, DIII.1d, DIII.1e	HR.3.1, HR.4	841.a
Compounding environment and procedures, maintenance and testing of equipment	DIII.3e, DIII.3f, DiII.3g	TX.5.1, TX.5.2, EC.2.9.3, EC.3.1	841.b,c,d
Storage of pharmaceuticals	DIII.3c, DIII.3h	EC.3.1	842.a,b,c
Access to library and reference materials	CIII.1i2	IM.9, IM.9.1	843.a

COMMUNITY HEALTH ACCREDITATION PROGRAM, INC.

ACCREDITATION SITE VISIT REPORT

Name of Organization:

Address:

Legal Structure:

Services Provided:

Provider #'s:

Principals:

Telephone #:
Fax #:
E – MAIL:

Site Visit Dates:

Site Visitors:

Accreditation Status:

Board of Review Dates:

Board of Review Determination:

EXHIBIT 3
OF 1 PAGES

Organizational Strengths

Organizational Challenges

Organizational Summary

Commendations (N =)

Definition: A citation that indicates an organization has exceeded the requirements of a specific CHAP Standard or Criterion.

Alpha/
Numerical
Identifier

_____

- **The Organization is commended for:**

_____

_____

_____

Evidence/Substantiation: _____

_____

_____

_____

- **The Organization is commended for:**

_____

_____

_____

Evidence/Substantiation: _____

_____

_____

Evidence/Substantiation: _____

_____

_____

_____

Required Actions (N =)

Definition: A definitive citation that indicates non-compliance by the organization with a specific CHAP Standards or Criterion. Immediate corrective action by the organization is necessary to rectify the situation

Alpha
Numerical
Identifier

_____

- **It is required that the organization:**

  _____
  _____
  _____

  Evidence/ Substantiation: _____
  _____
  _____
  _____

_____

- **It is required that the organization:**

  _____
  _____
  _____

  Evidence/ Substantiation: _____
  _____
  _____
  _____

_____

- **It is required that the organization:**

  _____
  _____
  _____

  Evidence/ Substantiation: _____
  _____
  _____
  _____

Previously Cited Required Actions Now Met (N =)

Alpha
Numerical
Identifier

_____

- **Previously cited Required Action :**

  _____
  _____
  _____

  Substantiation/Evidence: _____
  _____
  _____
  _____

PREVIOUSLY CITED REQUIRED ACTIONS NOT MET (N =)

Alpha
Numerical
Identifier

_____

Previously cited Required Action

_____
_____
_____

Substantiation/Evidence: _____
_____
_____
_____

_____

- **Continuing Required Action:**

  _____
  _____
  _____

  Substantiation/Evidence: _____
  _____
  _____
  _____

RECOMMENDATIONS

Definition: A statement of advisement that identifies a potential problem with a given CHAP Standard or Criterion that may increase in scope and severity if nor addressed.
This type of citation should be given serious consideration by the organization but change is not mandatory.

Alpha
Numerical
Identifier

_____

- **It is recommended that the organization:**

  _____
  _____
  _____

  Substantiation/Evidence: _____
  _____
  _____
  _____

_____

- **It is recommended that the organization:**

  _____
  _____
  _____

  Substantiation/Evidence: _____
  _____
  _____
  _____

CHAP

COMMUNITY HEALTH ACCREDITATION PROGRAM, INC.

ACCREDITATION FOR SITE VISIT REPORT

Name of Organization:	Children's Home Care, Inc.
Address:	4650 Sunset Blvd. Los Angeles, CA 90027
Legal Structure:	Corporation/Non-profit
Services Accredited:	Home Health Pharmacy
Provider #s:	Medicaid # 953956774 State License 980000709 Pharmacy Phy41727
Principals:	Dave Willcutts, CEO
Telephone #: **Fax #:** **E-Mail:**	(323) 669-2401 (323) 668-7976
Site Visit Date(s):	October 7 – 8, 2002; October 23 - 25, 2002
Site Visitors:	Gale Surrency, MA, RNC Marlene McDaniel, RPH, BSPH, MBA
Accreditation Status:	Initial
Board of Review Dates:	November 21 – 22, 2002

EXHIBIT 4
OF PAGES

SUMMARY

Children's Home Care, Inc. is a non-profit corporation established in 1993 as a provider of pediatric skilled nursing services, medical social work and pharmacy services. These services are delivered to children in age groups from birth to seventeen years, who live within a 30 mile radius of the Sunset Boulevard Los Angeles, California office. Revenues are generated from approximately 84% entitlement programs (MediCal, Children's Community Services and other partnerships), 13% state funded and 3% private pay.

In 1999, the organization experienced a decline in census. Restructuring of the organization began in 2000 and included creation of partnerships with biotechnical pharmaceutical companies which continue to contribute significantly to revenues of the organization. The administrative team consists of all newly hired personnel within the past two years (Vice President of Operations, Director of Patient Care Services and Education Coordinator).

In 2001 there were 1,961 skilled nursing and 3 social work visits to 429 children/families. The census in the Pharmacy program was 6. This represented an increase of 4% in nursing visits over the previous year and supported the organization's goal of controlled growth. The organization felt this was vital in order to establish a firm financial basis for expansion of the pharmacy infusion services as well as maintain quality of care to all clients.

Pharmacy services have undergone significant changes over the past 3 years. The volume of infusion and enteral therapy cases has increased dramatically. The Vice President of Operations is a registered pharmacist, who is the Administrator for both the Home Health and Pharmacy programs. The Director of Patient Care Services is responsible for the clinical pediatric home care operations and has extensive experience in this area.

Future plans include:

- Expansion of home infusion and nursing services to include other referral sources in addition to those from Children's Hospital;
- Increase growth of pharmacy services to manage a census of 250 clients with nursing support of home care pharmacy services;
- Expansion of chronic disease program;
- Assessing potential for expansion of the product line to include other infusion products for the pediatric population.

ORGANIZATIONAL STRENGTHS

1. Affiliation with a large pediatric specialty and teaching hospital which ensures family access to multiple resources and follow up care. The availability of professional consultation and educational resources for staff is also beneficial to clients and families.

2. Continuity of care between hospitalized children discharged to home care. Through contractual agreement, some of the acute care pediatric nurses are available for backup staffing for home care cases at times when case loads increase.

3. High level of primary caregiver satisfaction with delivery of pediatric services, as evidenced by interviews with families during home visits and review of satisfaction survey results.

4. Cross section of administrative, supervisory and field staff personnel have extensive experience in both pediatric acute and home care services.

ORGANIZATIONAL CHALLENGES

1. Diversification of referral sources through cultivation and establishment of other community referral sources to ensure long term viability. The organization's primary referral source is Children's Hospital of Los Angeles. Children's Home Care is located on site within the facility and is the preferred provider.

2. Recruitment and retention of competent skilled nursing and pharmacy staff for highly specialized pediatric services.

3. Development of a cohesive senior and mid-level management team, as three new staff hired within the past two years, transition into their leadership roles, mission and culture of the organization. Continued support at the executive level is vital to this team.

RECOMMENDATION (S) N=2

DEFINITION: **A statement that identifies a potential problem with a given standard that may increase in scope and severity if not addressed. A recommendation should be given serious consideration by the Agency, but changes are not mandatory.**

CIV.1b. **The planning process is consistent with organizational needs and includes:**

1. **goals and objectives;**
2. **priorities and strategies;**
3. **measurable outcomes;**
4. **action plans;**
5. **resource requirements**
6. **time frames; and**
7. **staff responsible for implementation.**

- CIV.1b. It is recommended that the Organization continue to develop the Business/Growth Plan and to ensure that all elements of the standard are included. The Board of Directors and the Vice President of Operations are in the process of drafting the 2002-2004 Plan. The draft version was presented to the site visitor during the survey and must be approved by the Executive Body.

CIV.2b. **Components to be evaluated annually include:**

1. **policies and procedures; (G244)**
2. **organizational structure and system; (G248)**
3. **achievement of goals;**
4. **demographics of clients served;**
5. **measurable client outcomes;**
6. **programs, including utilization and quality of services and products, appropriateness and adequacy, effectiveness and efficiency (including information about referrals not accepted); (G245)**
7. **human resources;**
8. **safety practices;**
9. **risk management;**
10. **financial resources and billing practices;**
11. **information systems;**

12. benchmarking.
(*42 CFR 484.52 - G244, G245, G248)

- CIV.2b. It is recommended that the Organization review the components of the standard to ensure that all items are captured in the Annual Report clearly. A review of the 2001-2002 Annual Report revealed that items 5, 8, 9 and 11 could be more clearly defined and stated in the Annual Summary. Information is being collected by the Organization and is available for inclusion in the Annual Evaluation Reports.

REQUIRED ACTION (S) N=13

DEFINITION: A statement that indicated non-compliance with CHAP Standards or Criterion.

CI.2b4. The governing body members and executive staff are required to disclose annually all matters of ownership interest, direct or indirect, which might reasonably result in a conflict of interest.

In addition, Hospice and Home Health agencies (Medicare Certified) evidence of annual disclosure includes the following:

a) names and addresses of individuals or corporations having a combined direct or indirect ownership or controlling interest of 5 percent or more in the agency or in any subcontractor in which the agency has a direct or indirect ownership interest of 5 percent or more;

b) the persons in (a) above who are related as spouse, parent, child or sibling;

c) the persons in (a) with an ownership or controlling interest in a Medicare or Medicaid facility;

d) the names and addresses of any officer, director or partner if the agency is a corporation or partnership;

e) conviction of any criminal offense involving Medicare, Medicaid or Title XX programs on the part of any person or organization in (a) and (c) above and on the part of any agent or managing employee of the agency;

f) the names and addresses of any current employees in managerial, accounting, auditing, or similar capacity who were employed by the agency's Medicare fiscal intermediary within the previous twelve months;

g) any changes within the previous year in Administrator, Director of Clinical Services or Medical Director;

h) the dates of the following: any change in ownership or control during the previous year or any anticipated changes in the coming year; any anticipated bankruptcy filings; and any changes in operations by a management company or leasing in whole or in part by another organization;

i) change of address for parent, subunits or branches.

(* 42 CFR 484.12(b) - G119, G120; 418.50(c) - L106)

- CI.2b4. It is required that governing body members annually disclose all matters of ownership which might reasonably pose a conflict of interest. This standard was not met, as there is no policy in place or documentation of annual disclosures signed by governing body and executive staff at the time of the site visit. During interview with the Board Chair, it was stated that governing body members sign disclosure statements; however, these documents were not available for review at the time of the site visit.

CI.4a. **The organization has a written public disclosure policy and makes at least the following available to the public:**

1. **ownership information; (G117)**
2. **philosophy and mission/purpose;**
3. **licensing, credentialing, and accreditation reports; (G117)**
4. **an annual report of services provided.**

(*42 CFR 418.50(c) - L106; 484.12 - G117)

- CI.4a. It is required that the organization have a written public disclosure policy which includes all elements of the standard. This standard was not met, as evidenced by the absence of a written policy, nor any mechanism to make the specified items other than the mission statement available upon request to consumers. The mission statement was found in selected brochures given to clients/families.

CI.4b. **A formal Client Bill of Rights is designed to recognize, protect, and promote the rights of each client to be treated with dignity and respect (G101). These rights may be exercised by the client or the client's representative (G104). The Client Bill of Rights must include the intent of each of the following statements: (G102) (See Public Health Standards for PH Bill of Rights.)**

The right to be fully informed orally and in writing of the following before care is initiated: (G101, G102)

1. **services/products and equipment available directly or by contract;**
2. **organization ownership and control;**

3. any specific charges for services to be paid by client and those charges covered by insurance, third-party payment or public benefit programs; (G113, G114)
4. billing policies, payment procedures and any changes in the information provided on admission as they occur within 15 days from the information date that the organization is made aware of change; (G115)
5. names and professional qualifications of the disciplines that will provide care and the proposed frequency of visits/service; (G108)
6. their right to participate in the plan for care and/or any change in the plan before it is made; (G108, G109)
7. the agency's policy on client advanced directives including a description of an individual's rights under State law (whether statutory description or as recognized by the courts of the State) and how such rights are implemented by the agency; (G110)
8. the organization's grievance procedures which includes contact names, phone numbers, hours of operation and how to communicate names, problems to the agency;

And the right to:

9. receive service without regard to race, creed, gender, age, handicap, sexual orientation, veteran status or lifestyle;
10. receive service without regard to whether or not any advance directive has been executed;
11. make informed decisions about care and treatment plans and to information in a way that is understandable to the client;
12. be notified in advance of treatment options, transfers, when and why care receiving will be discontinued; (G108)
13. receive and access services consistently and in a timely manner in accordance with organizations stated operational policy;
14. education, instructions and requirements for continuing care when services of the agency are discontinued;
15. participate in the selection of options for alternative levels of care or referral to other organizations, as indicated by the client's need for continuing care;
16. receive disclosure information regarding any beneficial relationships the organization has that may result in profit for the referring organization;

17. be referred to another provider organization if the organization is unable to meet the client's needs or if the client is not satisfied with the care they are receiving;
18. voice grievances regarding treatment, care or respect for property that is or fails to be furnished by anyone providing services on behalf of the organization without reprisal for doing so; (G106)
19. receive information on grievance procedures which includes contact name, phone numbers, hours of operation, how to communicate problems to the agency;
20. document a response from the agency regarding investigation and resolution of the grievance; (G107)
21. be advised of the availability, purpose and appropriate use of State, Medicare and CHAP Hotline numbers; (G116)
22. refuse treatment and be informed of potential results and/or risks;
23. not receive any experimental treatment without the client's specific agreement and full understanding of information explained;
24. be free from any mental, physical abuse, neglect or exploitation of any kind by agency staff;
25. have his/her property treated with respect; (G105)
26. confidentiality of his/her clinical records and the organization's policy for accessing and disclosure of clinical records; (G111, G112)
27. information regarding the organizations liability insurance upon request.

(*42 CFR 484.10 - G101, G102, G104-G116)

- CI.4b. It is required that the Client Bill of Rights or other admission documents contain all of the elements of the standard. This standard was not met, as evidenced by a review of the Client Bill of Rights and other admission documents which did not include elements 1, 2, 7, 12, 16, 20, and 27. This deficiency was corrected on site during the site visit.

CI.4g1b. **The purpose, function, and responsibilities of the designated group are outlined and available to staff.**

- CI.4g1b. (c/r CI.4g.1, CI.4g.3). It is required that the Organization orient staff to the role and function of the Ethics Committee and maintain documentation of the Ethics Committee review of ethical issues and reporting to the Governing Body of the issues. This standard was not met as evidenced by interviews with field and administrative staff, review of Governing Body Minutes, Ethics Policy #2010 and inservice documents. Interviews with field staff revealed a general knowledge deficit in relation to Ethics Committee function and role. Policy #2010 defines purpose, function and responsibilities of the Ethics Committee but does not stipulate how ethical issues are reviewed and reported to the Governing Body, or that staff receive the required orientation to organization's mechanism for addressing ethical concerns.

CII.7b1. Nursing done

Required work practice controls include: handwashing; bag technique; procedures for minimizing needle sticks; use of puncture resistant containers; decontamination or labeling of contaminated equipment before servicing or shipment.

- CII.7b1. (c/r CII.7b1b.) It is required that staff understand and adhere to work practice and infection control principles during the delivery of care in the home. This standard was not met, as evidenced by observation of 2 of 4 home visits (50%) during which nursing staff did not adhere to basic infection control techniques. The findings include:
  - Home Visit #1 – Observation of Phlebotomy (drawn from PICC line). Registered nurse used one pair of gloves to set up clean field, picked up used sharps container from bedside stand, then proceeded to clean PICC line cap and draw blood specimen with same gloves which had come in contact with soiled sharps container.
  - Home Visit #4 – Observation of Phlebotomy (drawn from PICC line) and PICC dressing change. During final cleansing of PICC line insertion site with 2 x 2 alcohol gauze pad, the soiled gloved fingers of the nurse's hand come in direct contact with the insertion site as the nurse cleansed outer portion of tube.

CIII.1g2. Individual personnel records or other agency records include:

a) evidence of individual qualifications; (G141)
b) evidence of multiple reference checks;
c) reports of police records search where required by state law;
d) evidence of current licensure, certification where applicable; (G141)
e) health reports as required by policies;
f) performance evaluations and competency evaluations (where applicable);
g) malpractice coverage for contract workers;
h) orientation, continuing education and inservice records;
i) other state or federal requirements, such as Immigration and Naturalization statement;
j) exit interviews (where applicable).

(*42 CFR 484.14(e) - G141)

- CIII.1g2. (c/r HHIII.1b3.) It is required that personnel files or other organizational records contain evidence of professional skill competency testing and continuing education/inservice documentation. This standard was not met, as evidenced by review of 13 of 17 personnel files (76%) which did not contain evidence of routine competency testing and documentation of ongoing inservices/continuing education for staff. The Organization has developed a new form and has begun to competency test professional staff.

CIII.1h. An annual formal performance evaluation is completed on all employees by the appropriate supervisor with active employee participation. It is signed by both parties. Such evaluations include:

1. employee self-evaluation;
2. supervisor's assessment of employee fulfillment of respective job responsibilities and requirements;
3. employee development planning;
4. individual goal setting and quality achievement review;
5. participation in quality improvement activity;
6. on-site evaluation reports (clinical or field evaluation for service delivery staff);
7. response to performance evaluation by employee.

- CIII.1h. It is required that annual performance evaluations contain evidence of employee self-evaluations. This standard was not met, as evidenced by a review of 7 of 18 nursing and pharmacy personnel files (38%) which did not contain evidence of self-evaluations. This deficiency was addressed during the site visit, and self-evaluations were being completed for all staff.

CIII.1j4. **All contracts and agreements are reviewed annually and updated as necessary.**

- CIII.1j4. It is required that contracts/agreements be reviewed annually and updated as necessary. This standard was not met, as evidenced by a review of 3 contracts which revealed that contracts had not been reviewed since 1996. Contracts reviewed were social workers, and laboratory contracts with Unilab and Children's Hospital of Los Angeles.

HHI.2b2. **The responsibilities of the professional group include:**

a) **establishment and annual review of policies governing the scope of services offered, admission and discharge criteria, medical supervision and plans of care, clinical protocols, emergency care, clinical records, and personnel qualifications;**
b) **participation in annual program evaluations;**
c) **meeting quarterly;**
d) **meetings are documented by dated minutes.**

(42 CFR 484.16(a) - G153, G154, G155; 484.52 - G243)

- HHI.2b2. It is required that the Professional Advisory Group meet quarterly. This standard was not met, as evidenced by a review of Professional Advisory minutes and interviews with staff which revealed past practice of annual meetings. To date, there has been one meeting held (4/26/02) with one additional meeting planned for 12/02. The Organization has revised the policy to reflect quarterly meetings which will begin to be implemented in 2003.

HHII.5c. **Discharge summaries are completed on all clients released from services with copies forwarded to the client's physician. Summaries include:**

1. **brief history which reflects the reason for admission;**
2. **summary of services provided;**

3. **current status of patient in relation to goals/outcomes;**
4. **continuing care needs;**
5. **current medications and allergies;**
6. **instructions given to patient.**

o HHII.5c. (c/r HHII.5b.) It is required that Discharge/Transfer Summaries include all of the elements of the standard. This standard was not met, as evidenced by a review of 4 of 4 discharge/transfer records (100%) which did not include the following items:

1. brief history which reflects reason for admissions to home care;
2. instructions given to primary caregiver at time of discharge. The Organization uses one form to record discharge/transfer information. Only one record out of four contained an addendum to the Summary which explained instructions given to family;
3. findings, teaching and responses to teaching during the course of services provided by home care;
4. medications, diet and allergies;
5. services provided by other organizations (when applicable) to transfer clients.

HHIII.1b1. Professional staff show evidence of graduation from appropriate courses of study, preferably from schools accredited by their respective professional associations. (42 CFR 484.12(c) - G121)

o HHIII.1b1. It is required that professional staff show evidence of graduation from appropriate courses of study as verified by diploma or transcript or other appropriate documentation specific to the state. This standard was not met, as evidenced by a review of 12 of 17 personnel files (70%) which did not contain such documentation. The Organization had begun to correct this deficiency during the site visit.

DII.6a. The Home Pharmacy Program has a quality improvement program which is designed to identify strategic and at-risk activities, establishes monitoring parameters for these activities, establishes minimal standards or criteria to be met, and describes methods used to improve the quality of service.

- DII.6a. (c/r 6b.). It is required that the pharmacy have a Quality Improvement plan that is organized and meets stated parameters. This standard was not met, as a documented plan does not exist and there is no meaningful history of Quality Improvement activities to meet this standard, although recent efforts have begun to develop this process.

DIII.3b. Drug preparation work areas are adequate and clean.

- DIII.3b. It is required that "clean" equipment and supplies be stored separately from "dirty" areas used to clean and process equipment. This standard was not met, as evidenced by observation of the "dirty" area used for cleaning pumps from patient homes, during which it was noted that fresh boxes of sterile syringes and other supplies were stored in the designated "dirty" area. This deficiency was corrected while the pharmacy site visitor was on site.

Joint Commission
on Accreditation of Healthcare Organizations
Setting the Standard for Quality in Health Care

May 30, 2003

Terry A. Duncombe, RN, MSHA
President/CEO
Community Health Accreditation Program
39 Broadway, Suite 710
New York, NY 10006

Dear Ms. Duncombe:

I am writing to advise the Community Health Accreditation Program (CHAP) of recent developments in the Joint Commission's Cooperative Accreditation Initiative (CAI). Earlier this month, the Joint Commission evaluated CHAP's plans to require its organizations to conduct Public Information Interviews at least once during each three-year accreditation cycle. We believe that this process is comparable to the existing JCAHO requirement, and as such we have determined that CHAP is in compliance with the additional CAI participation requirements first promulgated in 1999. Compliance with this and other expectations will of course be subject to verification during observation surveys.

The Joint Commission has also completed an evaluation of CHAP's Hospice program standards in comparison to existing JCAHO Hospice standards. CHAP has agreed to make a number of modifications that will result in general comparability between the standards of our two organizations. As a result, the Joint Commission will now extend recognition under the CAI to CHAP's Hospice accreditation program. The Joint Commission will now accept an organization's CHAP accreditation for the following home care services: home health, personal care, support, pharmaceutical dispensing, consultant pharmacy, home medical equipment, clinical respiratory and hospice. The Joint Commission will continue to conduct evaluations of an organization's long term care pharmacy, ambulatory infusion and rehab technology programs, even if the organization is CHAP accredited.

Recently, the Joint Commission has announced a number of accreditation process changes, called Shared Visions-New Pathways, designed to facilitate increased patient safety and quality improvement in our accredited organizations. The JCAHO Executive Committee has concluded that three (3) of these new or planned policies/survey process changes are appropriate requirements for all CAI partners that wish to maintain JCAHO recognition under the Comparable Accreditation track. The three additional participation requirements are described as follows:

National Patient Safety Goals. Participating accrediting organizations will be required to periodically identify and require compliance with safety goals and associated recommendations

One Renaissance Boulevard
Oakbrook Terrace, IL 60181
(630) 792-5000
http://www.jcaho.org

EXHIBIT 5
OF PAGES

appropriate for the settings and services they accredit. These goals will need to be consistent with the published Serious Events or Safe Practices identified by the National Quality Forum.

Periodic Performance Reviews. Participating accrediting organizations will be required to develop the capability to receive, evaluate and respond to intra-cycle submissions of standards compliance data from accredited organizations, including corrective action plans to address identified areas of standards non-compliance.

Unannounced Regular Surveys. Participating accrediting organizations will be required to conduct all regular accreditation surveys with no advance notice by Jan. 1, 2006.

For the National Patient Safety Goals and Periodic Performance Review expectations, we would expect CHAP to demonstrate comparable processes within one year from the date of this letter. As for the Unannounced Regular Survey expectation, we would expect to receive a commitment from CHAP within one year from the date of this letter of its intention to implement unannounced regular surveys beginning no later than Jan. 1, 2006.

We appreciate the commitment you have demonstrated to achieve comparability with the 1999 additional requirements. We look forward to working with you during the next year to achieve compliance with new expectations designed to create an even greater culture of safety and quality improvement in our mutually-accredited organizations. I will be contacting you in the near future to provide clarifying information on the new requirements. In the meantime, please feel free to contact me with any questions.

Sincerely,

Mark A. Crafton

Mark A. Crafton, MPA
Director, State Relations
Division of Business Development, Government & External Relations

cc: Dennis O'Leary, M.D.
Charles Mowll, FACHE
Maryanne Popovich
Gale Surrency, CHAP

Attachment B

THE AMERICAN COUNCIL ON PHARMACEUTICAL EDUCATION
20 North Clark Street, Suite 2500 • Chicago, Illinois 60602-5109 • www.acpe-accredit.org
312/664-3575 • FAX 312/664-4652

February 28, 2003

Dear Colleague:

As you have been notified, in response to a request from the Council on Credentialing in Pharmacy (CCP), the Board of Directors of the American Council on Pharmaceutical Education (ACPE) has agreed to initiate **a profession-wide dialog concerning the possible development of national standards and an accreditation process for pharmacy technician education and training**. The decision was taken at the Council's board meeting held this January. ACPE is the national agency for the accreditation of professional degree programs in pharmacy, and providers of continuing pharmaceutical education. Further information about ACPE and its operations can be found on our website www.acpe-accredit.org. ACPE is asking for your feedback on this important process. The current diversity of qualifications, knowledge, responsibilities and regulation of pharmacy technicians will create both challenges and opportunities as the profession seeks to envision the proper quality assurance process for technician education and training. **ACPE recognizes the need to initiate the dialog with no pre-conceived ideas regarding the final outcome**. For the details on providing ACPE your thoughts on this issue, please continue…

Invitation to Comment

ACPE invites your organization to submit written comments and suggestions that you feel should be taken into consideration as the profession explores the issue of pharmacy technician education and training. We would also request that you publicize this request for comment to your relevant constituencies. We are seeking input from as wide an audience as possible. This invitation to comment has been sent to pharmacy organizations and foundations, colleges and institutes offering pharmacy technician training programs, schools and colleges of pharmacy, providers of continuing pharmacy education, and credentialing and accreditation agencies involved with pharmacy technicians. Individuals are also invited to comment.

For the purposes of the initial comment period, we request that written comments be submitted **as soon as possible but no later than October 31, 2003** to allow adequate time for the compilation of a summary before ACPE's January 2004 board meeting.

Open Hearings

The first in a series of open hearings is scheduled to take place at the annual meeting of the American Pharmaceutical Association in New Orleans, LA on Monday March 31, 2003. If you would like ACPE to convene an open hearing at one of your meetings, please contact us so that we discuss this further with you. Details of future open hearings will be publicized as and when arrangements are finalized.

Background Materials

The recently published White Paper on Pharmacy Technicians, endorsed by the 12 pharmacy organizations of CCP, identified several outstanding issues relating to pharmacy technicians. Many of the issues raised in the White Paper were further discussed at a summit on pharmacy technicians in May 2002. Along with the White Paper, the summit report is recommended reading. The references for these documents are on the enclosure.

On behalf of ACPE, we thank you for your contribution to this important exercise. We look forward, with your help and input, to identifying the best course of action, not only for the profession of pharmacy, but also for the promotion of public health and the better use of medications.

Please contact us if we can be of further assistance.

Yours truly,

Peter H. Vlasses, Pharm. D.

Peter H. Vlasses, PharmD, BCPS, FACCP
Executive Director

Mike Rouse, BPharm (Hons), MPS
Assistant Executive Director
International & Professional Affairs

Enclosed: ACPE Invitation to Comment: Education and Training of Pharmacy Technicians

The American Council on Pharmaceutical Education

Invitation to Comment: Education and Training of Pharmacy Technicians

Following a request from the Council on Credentialing in Pharmacy (CCP), the American Council on Pharmaceutical Education (ACPE) has agreed to initiate a profession-wide dialog concerning the possible development of national standards and an accreditation process for pharmacy technician education and training.

Outline of the Process

Subject to a decision on whether or not to proceed with the development of national standards *(a decision which is expected to be taken in January 2004)*, ACPE believes that the whole process, from initiation to implementation, could take about three years. In broad terms the process will be as follows:

Year 1 (2003) ACPE will solicit written comments from pharmacy organizations and individuals and convene a series of open hearings. Comments submitted will be analyzed and summarized.

Year 2 (2004) *If warranted based on the feedback of the previous year*, ACPE will develop and publish a draft set of competency-based standards for pharmacy technician education and training. ACPE will solicit comments on the draft standards from pharmacy organizations and individuals in written form and in open hearings meetings, and re-draft the standards based on feedback received.

Year 3 (2005) ACPE will invite final review of the revised standards by the professional organizations, adopt the standards and initiate the process to accredit pharmacy education and training programs. ACPE will initiate a process for the development of "distinctive standards" for continuing education providers that wish to conduct accredited continuing education programs for pharmacy technicians.

Invitation to Comment

ACPE is hereby inviting organizations and individuals to submit written comments and suggestions that they feel should be taken into consideration as the profession discusses this issue. Official documents and policy statements are also welcome. Comments may cover any area relevant to pharmacy technicians, but ACPE requests that respondents focus on the questions and areas listed below. It is anticipated that other discussions, which are outside of ACPE's specific terms of reference, may also be required. When compiling your comments, please consider the future of pharmacy technicians, not only the present.

Questions to be Considered

1. Definition

   The 2002 White Paper[1] lists the following definition:

   A pharmacy technician is an individual working in a pharmacy setting who, under the supervision of a licensed pharmacist, assists in pharmacy activities that do not require the professional judgment of a pharmacist.

   Is this definition appropriate and adequate? How could it be improved to better define pharmacy technicians, and reflect what is happening and required in practice, both now and in the future?

2. Levels of Pharmacy Support Personnel*

   Should different levels of pharmacy support personnel (* not including clerical, accounting and housekeeping functions) be defined? If so, what should these be? What additional definition(s) would be applicable?

3. Roles, Responsibilities and Competencies of Pharmacy Support Personnel

   For each level of pharmacy support personnel identified in #2 above, describe the roles, responsibilities and required competencies.

4. Education

   Education involves a deep understanding of a subject, based on explanation and reasoning, through systematic instruction and teaching.[1]

   For each level of pharmacy support personnel identified in #2 above, describe the required education, including eligibility requirements and continuing education.

5. Training

   Training involves learning through specialized instruction, repetition and practice of a task, or series of tasks, until proficiency is achieved .[1]

   For each level of pharmacy support personnel identified in #2 above, describe the required training, including eligibility requirements.

6. Quality Assurance of Pharmacy Technician Education and Training

   For the education and training of pharmacy technicians described in #4 and #5 above, what is/are the most appropriate system(s) of quality assurance?

Attachment C

California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GRAY DAVIS, GOVERNOR

LICENSING COMMITTEE
AD-HOC Committee on Pharmaceutical Benefit Managers (PBMs) Regulation

Meeting Summary

DATE: June 4, 2003

TIME: 9:00 a.m. – 12 noon

LOCATION: 400 Street, Suite 4070
Sacramento CA 95814

Ad Hoc Committee Members: Bill Powers, Public Member
Andrea Zinder, Public Member (absent)
Caleb Zia, Ex-Officio Member

Board Member and Facilitator: Dave Fong, Pharm.D.

Staff Present: Patricia Harris, Executive Officer
Ronald Diedrich, Deputy Attorney General

Introductions

Board member Dave Fong stated that the purpose of the ad-hoc committee is to gather facts to determine whether PBMs should be regulated. This means the board must demonstrate that the purpose of regulation is necessary to protect the public and ensure patient safety. Another reason to regulate would be if the PBM activities were considered the practice of pharmacy.

The committee held its first meeting in March. This second meeting is to explore the development of formularies, the requirements of the Pharmacy & Therapeutics (P & T) Committees including the qualifications of its members, the process used by the PBM to select the drugs that are on the formulary and how cost factors in this selection process. It was explained that a formulary is a pre-approved list of prescription drugs established by the PBM through a P & T Committee process.

Dr. Fong added that his role is facilitator for this ad hoc committee. The committee is comprised of the board's public members and is functioning under the auspices of the Licensing Committee. He also explained that Board President John Jones asked former public board member Caleb Zia to continue to serve on this committee as an ex-officio member.

Dr. Fong stated that guest speakers were invited to speak on the topic of formulary development.

Department of Managed Health Care (DMHC)

Warren Barnes, Legal Counsel at DMHC stated that they regulate Knox-Keene health care service plans. DMHC's experience with PBMs is indirect with no authority to regulate PBMs, IPAs or medical groups. However, the department's regulation of health care service plans has a significant indirect effect on PBMs because PBMs subcontract with health care service plans to manage the pharmacy benefit for its enrollees. The department does not regulate the financial solvency of the PBM nor any of the activities that the PBM is engaged in.

California does not require that a health care service plan provide an outpatient drug benefit. However, if the health plan provides this benefit, then DMHC regulates the benefit. The plan must cover all medically necessary drugs. Historically, pharmaceutical benefits have been provided on a two-tier basis. Currently, the vast majority of health plans have added a third tier of prescription drug coverage that includes any drug that is basically FDA approved and its prescribed use is consistent with standards of practice. With a three-tier plan, patients have broad access to and choice of prescription drugs, but pay different co-payments (i.e. the lowest co-pay is for generic drugs; the next highest co-pay is for formulary or preferred drugs; the highest co-pay is for "non-preferred" and non-formulary drugs).

While DMHC does not regulate the development of a formulary, the health plan must offer an appeal process for non-covered drugs based on medical necessity. This is an independent medical review by a neutral third party. Mr. Barnes reported that state approval is required for the drug benefit design and any significant changes to the plan design or administration of the program. If a plan has a prescription benefit and wants to either limit the benefit in any way or exclude any drug, then it has to submit a material modification to DMHC to get approval for the change. The material modification is a formal process that requires approval before the change to the prescription benefit can be implemented. If the plan can prove that DMHC approved a change, then the enrollee cannot appeal a plan's decision for non-coverage.

Mr. Barnes noted that the Department of Insurance regulates insurance companies that provide health benefits. Self-funded employer welfare benefit plans (which also provides drug benefits) are under the jurisdiction of the U.S. Department of Labor, which regulates activities such as claims payment, member appeals and coverage decisions. While PBM activities related to such plans are governed by the client's compliance with these standards, these other agencies do not have the same regulatory oversight over drug benefits, as does the DMHC. However, it was noted that the Department of Labor recently issued regulations that were specific to medical exceptions and non-covered benefits including pharmacy benefits that require the PBM or employer to accept complaints, appeals, and grievances.

Department of Health Services – Medi-Cal

Doug Hillblom, Chief of the Medi-Cal Contracts Section, spoke on the Medi-Cal fee-for-service program for prescription drugs. He stated that it is a prior authorization program that is

permitted by the federal Medicaid laws. This means every drug product is available to Medicaid beneficiaries through prior authorization. California has a list of contract drugs that do not require prior authorization. This is a supplemental contract to the CMS Medicaid rebates. California has the largest supplemental rebate program in the nation.

The federal Medicare program has a different purpose than a PBM. Medi-Cal's purpose is to ensure access for eligible patients while controlling costs. In many instances, Medi-Cal will have multiple products in a class of drugs while the private insurer may have one. A private insurer may have a co-payment arrangement. While Medi-Cal does have a co-payment of $1 per prescription, if the beneficiary cannot afford the $1, the provider cannot deny service.

California has in law a list of 5 criteria that must be used to review every drug. They are: essential need (what is the essential need of that drug product as compared to the current list of drugs), safety (safety of comparable products), efficacy, misuse potential (more appropriate alternative than costly use as first line for therapy), and cost. He stated there are two processes for review. The first review involves the therapeutic category. Information on the each drug is reviewed for the five criteria. If there is not any substantial therapeutic difference, then all the drugs will be placed on the formulary. If there is a substantial cost difference, then it will not be placed on the formulary. However, the physician can still prescribe the drug but must obtain a treatment authorization review (TAR) for approval to prescribe the drug.

The provider submits the TAR, which must include the diagnosis and the drug therapy that has been tried or considered. A pharmacist then reviews the TAR. Approximately 220,000 TARs are received a month. The review process takes 24 hours and approximately 10% are rejected.

Dr. Hillblom explained that the Medi-Cal process is open. What is not open is the contract information. This is proprietary information because disclosure would limit the manufacturer's ability to be competitive in the marketplace. DHS also has a Medi-Cal Advisory Committee comprised of physicians and pharmacists that advises DHS on formulary issues.

DHS is able to lower the price of drugs due to its ability to move market share. However, unlike the private sector, Medicaid has state and federal mandated price controls.

Mr. Hillblom stated that Medicaid is guaranteed rebates. Drug prices are based on the best price. The best price is based on the market place. For example, a PBM negotiates a price with a drug manufacturer for an innovator drug that is the lowest price in the nation. This negotiated price then becomes the best price for Medicaid. Then Medicaid takes the average manufacturer's price minus 15.1 percent and compares it to the best price. Whichever rebate is greater becomes the Medicaid rebate. This is the initial point of negotiations for the supplemental rebate. The drug manufacturer has a contract with the federal government that discloses the best price and to ensure compliance, the manufacturer may be subject to audit by the Office of the Inspector General.

Concerns were raised about comparing the Medicaid program to the commercial market. Because the rules for Medicaid are so restrictive, all drugs are placed on prior authorization and

then negotiated off to be placed on the formulary. To require a prior authorization for private healthcare would be costly. While the goals for the public and private sector are the same to provide quality and affordable prescription benefits, the private insurer does this with a formulary and an appeal process for medically necessary drugs not covered by the formulary.

Caremark – PBM

Joseph Addigo introduced himself as the Chief Medical Officer for Caremark, Chair of Caremark's P&T Committee and a licensed California physician. Caremark administers the pharmacy benefits for CalPERS. Caremark has a network of 55,000 pharmacies.

Dr. Addigo discussed the October 2000 document title *Principles of a Sound Drug Formulary System* as a template for his presentation. He stated that Caremark uses this document as the basis for its formulary process. He emphasized that the P&T committee process is not just developing a list of drugs. It is an ongoing, day-to-day management process for quality and cost control to ensure patient access to good medical care. The committee meetings are live and regular. There are special meetings in addition to scheduled monthly and quarterly meetings and Caremark has an infrastructure that supports this process.

The goal of the formulary process is to provide patients with the highest quality of care with minimal hassle to the physician and a system that supports the doctor-patient relationship. Caremark has a P & T Committee with a diverse and demographically represented membership. It is a 17-member committee. There are 13 voting members that are active practitioners. Eleven are physicians and 2 members are pharmacists. The 4 non-voting members are Caremark employees. The members are kept anonymous so that the pharmaceutical industry does not know who is on the committee.

The P & T Committee has a standardized series of documents that are used to review all the medical information for every single formulary decision. There is a cadre of pharmacists who are the power behind developing all the data that P&T voting committee reviews. The pharmacists develop significant monographs, perform extensive literature searches, and review all the research on each drug. If the committee doesn't have a member with expertise in a specific area, then they have a guest consultant who is and who can provide in-depth review.

Once the P & T Committee makes a decision and the quality of the drugs being considered therapeutically equivalent, then cost becomes a factor. If there is a product that is proven clinically and scientifically better, that drug is placed on the formulary even if it is more expensive.

A comment was made that there is an ongoing hassle factor for pharmacists when a prescription drug is no longer covered on the formulary or the co-pay has changed. Usually the patient is unaware of the change at the time the prescription is being filled. Caremark responded that when a drug is removed from the formulary for safety reasons, this information is immediately communicated to the plan, the patients and the providers. While Caremark added that it has a communication system in place to keep everyone informed of any changes, they agreed that

there is always room for improvement. Until the entire prescribing and dispensing process is electronic, it is going to be difficult to completely eliminate this problem. However, Caremark felt that by using a tiered formulary system, very few drugs are not covered and while the drugs might be available but at a different co-payment, this system tends to remove some of the hassle factors as well.

Caremark stated that it has a national formulary and drug lists that are fine tuned even further for some clients. Ultimately, it is the client who decides on the drug benefit design. Only a small percentage of Caremark's clients make changes to the preferred product listing. These changes are typically found in the lifestyle drugs.

The PBM clients (who are the employers) also look at how the PBM manages the plan. The clients are identifying the value of the preferred product listing process and look to see if the PBM has misaligned incentives or relationships with the pharmaceutical manufacturer. Caremark is an independent PBM and is not associated with a pharmaceutical manufacturer. Caremark's business model demonstrates the importance of quality first and then focuses on the financial value of the process. Caremark encourages generics and mail service because of the deeper discounts. The clients usually have consultants that advise them on the benefit design. The client looks to see how the PBM manages the product component and the utilization and what clinical management programs are in place to ensure appropriate drug therapy. Today the clients are much more sophisticated and the PBM must demonstrate its value on a variety of fronts.

Concern was expressed regarding the relationship of some PBMs with the drug manufacturers and that the rebates or cost savings are not being passed on to the client. It was expressed that formulary decisions are based on cost factors only after the safety, efficacy and therapeutic need have been established. It was stated that the drug manufacturer is the vendor, while the employer is the client. It is the PBM's responsibility to get the best price for its client. Caremark's business model negotiates with pharmaceutical companies and takes their discount arrangements in the form of a discount from cost of goods sold. Dr. Yargerman stated that they do not accept administrative fees. Caremark builds a financial package depending on each individual client's needs and what is competitive in the marketplace that provides the best benefit design for the client.

Dr. Addigo stated that it his and Caremark's perspective that the guidelines and process that they follow to develop a formulary is so highly unbiased and clinically credible because the physicians and pharmacists of the P&T Committee make the decisions. The pharmacists and physicians should be making the formulary decisions separate and apart from any financial considerations and negotiations. It is in the best interest of the client to develop a formulary based on quality and then separately and independently negotiate the price. The PBM is able to do this and keep prices competitive for the client through an effective formulary process.

Additional Comments
It was suggested that the Board of Pharmacy take a leadership role and facilitate meetings with employers, PBMs, and providers to improve communications so that the "noise" is minimized at the pharmacy level. It was noted that there is such a coalition at the national level that involves many of the national pharmacy organizations.

A statement was made that employers have not been represented at these meetings and it is unknown if they are unhappy with PBMs and the process. Dr. Fong responded that the Pacific Business Group and CalPERs were invited.

A comment was made that the committee also has not heard from the unhappy patients who learn that a drug that was covered last month is no longer covered, or is covered but at a higher co-pay. It is the pharmacist and pharmacy personnel that are on the receiving end of the patient's unhappiness, not the PBM. It is the pharmacy staff that becomes the representative of the PBM.

It was also noted that the reason for the ground swell for regulation by pharmacy providers is because they are unhappy with their inability to negotiate for the reimbursement rate. The pharmacy provider is told by the PBM -- here is the contract and you have 14 days to sign if you want to participate in the network. Also, resident pharmacies are not given the same opportunity to compete with the mail service pharmacies in a network.

The PBM must balance the needs of the employer who wants to control costs and the patient who wants access. The board's responsibility is to ensure patient safety and the quality of care and patient safety.

Recommendations
The committee stated that it would discuss recommendations at the July board meeting.

Part C1 – Sunrise Criteria and Questions

The following questions have been designed to allow presentation of data in support of application for regulation. Provide concise and accurate information in the form indicated in the *Instructions* portion of this questionnaire.

I. UNREGULATED PRACTICE OF THIS OCCUPATION WILL HARM OR ENDANGER THE PUBLIC HEALTH SAFETY AND WELFARE

12. Is there or has there been significant public demand for a regulatory standard? Document. If not, what is the basis for this application?

13. What is the nature and severity of the harm? Document the physical, social, intellectual, financial or other consequences to the consumer resulting from incompetent practice.

14. How likely is it that harm will occur? Cite cases or instances of consumer injury. If none, how is harm currently avoided?

15. What provisions of the proposed regulation would preclude consumer injury?

II. EXISTING PROTECTIONS AVAILABLE TO THE CONSUMER ARE INSUFFICIENT

16. To what extent do consumers currently control their exposure to risk? How do clients locate and select practitioners?

17. Are clients frequently referred to practitioners for services? Give examples of referral patterns.

18. Are clients frequently referred elsewhere by practitioners? Give examples of referral patterns.

19. What sources exist to inform consumers of the risk inherent in incompetent practice and of what practitioner behaviors constitute competent performance?

20. What administrative or legal remedies are currently available to redress consumer injury and abuse in this field?

21. Are the currently available remedies insufficient or ineffective? If so, explain why.

III. NO ALTERNATIVES TO REGULATION WILL ADEQUATELY PROTECT THE PUBLIC

22. Explain why marketplace factors will not be as effective as governmental regulation in ensuring public welfare. Document specific instances in which market controls have broken down or proven ineffective in assuring consumer protection.

23. Are there other states in which this occupation is regulated? If so, identify the states and indicate the manner in which consumer protection is ensured in those states. Provide, as an appendix, copies of the regulatory provisions from these states.

24. What means other than governmental regulation have been employed in California to ensure consumer health and safety. Show why the following would be inadequate:
    a. code of ethics
    b. codes of practice enforced by professional associations
    c. dispute-resolution mechanisms such as mediation or arbitration
    d. recourse to current applicable law
    e. regulation of those who employ or supervise practitioners
    f. other measures attempted

25. If a "grandfather" clause (in which current practitioners are exempted from compliance with proposed entry standards) has been included in the regulation proposed by the applicant group, how is that clause justified? What safeguards will be provided consumers regarding this group?

IV. REGULATION WILL MITIGATE EXISTING PROBLEMS

26. What specific benefits will the public realize if this occupation is regulated? Indicate clearly how the proposed regulation will correct or preclude consumer injury. Do these benefits go beyond freedom from harm? If so, in what way?

27. Which consumers of practitioner services are most in need of protection? Which require least protection? Which consumers will benefit most and least from regulation?

28. Provide evidence of "net" benefit when the following possible effects of regulation are considered:
    a. restriction of opportunity to practice
    b. restricted supply of practitioners
    c. increased costs of service to consumer
    d. increased governmental intervention in the marketplace.

Part C2 – Rating on Sunrise Criteria

Assign each Criterion a numeric rating of 0–5 in the space provided. The rating should be supported by the answers provided to the questions in *Part C1*. Scale descriptions are intended to give examples of characteristics indicative of ratings.

0____1____2____3____4____5
(*Little Need for Regulation*) LOW HIGH (*Great Need for Regulation*)

I. UNREGULATED PRACTICE OF THIS OCCUPATION WILL HARM OR ENDANGER THE PUBLIC HEALTH SAFETY AND WELFARE ____

low: Regulation sought only by practitioners. Evidence of harm lacking or remote. Most effects secondary or tertiary. Little evidence that regulation would correct inequities.

high: Significant public demand. Patterns of repeated and severe harm, caused directly by incompetent practice. Suggested regulatory pattern deals effectively with inequity. Elements of protection from fraudulent activity and deceptive practice are included.

II. EXISTING PROTECTIONS AVAILABLE TO THE CONSUMER ARE INSUFFICIENT ____

low: Other regulated groups control access to practitioners. Existing remedies are in place and effective. Clients are generally groups or organizations with adequate resources to seek protection.

high: Individual clients access practitioners directly. Current remedies are ineffective or nonexistent.

III. NO ALTERNATIVES TO REGULATION WILL ADEQUATELY PROTECT THE PUBLIC ____

low: No alternatives considered. Practice unregulated in most other states. Current system for handling abuses adequate.

high: Exhaustive search of alternatives finds them lacking. Practice regulated elsewhere. Current system ineffective or nonexistent.

IV. REGULATION WILL MITIGATE EXISTING PROBLEMS ____

low: Little or no evidence of public benefit from regulation. Case not demonstrated that regulation precludes harm. Net benefit does not indicate need for regulation.

high: Little or no doubt that regulation will ensure consumer protection. Greatest protection provided to those who are least able to protect themselves. Regulation likely to eliminate currently existing problems.

V. PRACTITIONERS OPERATE INDEPENDENTLY, MAKING DECISIONS OF CONSEQUENCE ____

low: Practitioners operate under the supervision of another regulated profession or under the auspices of an organization which may be held responsible for services provided. Decisions made by practitioners are of little consequence.

high: Practitioners have little or no supervision. Decisions made by practitioners are of consequence, directly affecting important consumer concerns.

VI. FUNCTIONS AND TASKS OF THE OCCUPATION ARE CLEARLY DEFINED ____

low: Definition of competent practice unclear or very subjective. Consensus does not exist regarding appropriate functions and measures of competence.

high: Important occupational functions are clearly defined, with quantifiable measures of successful practice. High degree of agreement regarding appropriate functions and measures of competence.

VII. THE OCCUPATION IS CLEARLY DISTINGUISHABLE FROM OTHER OCCUPATIONS THAT ARE ALREADY REGULATED ____

low: High degree of overlap with currently regulated occupations. Little information given regarding the relationships among similar occupations.

high: Important occupational functions clearly different from those of currently regulated occupations. Similar non-regulated groups do not perform critical functions included in this occupation's practice.

VIII. THE OCCUPATION REQUIRES POSSESSION OF KNOWLEDGES, SKILLS AND ABILITIES THAT ARE BOTH TEACHABLE AND TESTABLE ____

low: Required knowledge undefined. Preparatory programs limited in scope and availability. Low degree of required knowledge or training. Current standard sufficient to measure competence without regulation. Required skill subjectively determined; not teachable and/or not testable.

high: Required knowledges clearly defined. Measures of competence both objective and testable. Incompetent practice defined by lack of knowledge, skill or ability. No current standard effectively used to protect public interest.

IX. ECONOMIC IMPACT OF REGULATION IS JUSTIFIED ____

low: Economic impact not fully considered. Dollar and staffing cost estimates inaccurate or poorly done.

high: Full analysis of all costs indicate net benefit of regulation is in the public interest.

[1] *See Eli Lilly*, 61 Fed. Reg. 31,117 (June 19, 1996); *See In the Matter of Merck & Co., Inc., and Merck-Medco Managed Care*, 951-0097 (1998).

[2] *United States ex. rel. Hunt v. Merck & Co. Inc.*, E.D. Pa., Mo. 00-737, *notice of intervention* 6/23/03.

[3] *See* First Amended Representative Action and Complaint for Violations of the Unfair Competition Law, available at http://www.hagens-berman.com/files/PBM%20Complaint%20-%20Amended%20-%20NP10497 38021600.pdf (last visited July 3, 2003).

[4] Cal. Bus. & Prof. Code § 17200 (West 2002).

[5] *See* Medicare-Medicaid Anti-Fraud and Abuse Amendments, 42 U.S.C. § 1320a-7b(b) (2003).

[6] See *Bates v. State Bar of Arizona*, 433 U.S. 350 (1977); *FTC v. Indiana Federation of Dentists* , 476 U.S. 447 (1986).

[7] Bates, 433 U.S. at 364.

[8] 16 C.F.R. 453 et seq.; 16 C.F.R. 310.

[9] *Id.*

Drug Topics® Archive
Jul. 7, 2003

GOVERNMENT and LAW

Another state passes law to regulate PBMs

A new Maine law, signed by the governor in June, establishes ethical standards for pharmaceutical benefit managers, including requiring the full disclosure of potential conflicts of interest.

"The law's most significant element is that it makes very clear that PBMs have a fiduciary responsibility to the people they contract with," said John Rector, general counsel for the National Community Pharmacists Association. "Lately, PBMs have been claiming in suits against them that they have no such duty."

The Maine legislation, titled "An Act to Protect Against Unfair Prescription Drug Practices," is the third state law in a little over a year to address the governance of PBMs, and it is the most far-reaching. A Georgia law adopted in May 2002 requires PBMs to be licensed by the state board of pharmacy. A Maryland law adopted this May requires the state insurance commissioner to examine PBMs at least every three years.

The net effect of both laws, and the Maine law, is to bring PBM practices under the scrutiny of the state regulators, said Rector. "The legislatures wanted to be confident that PBMs are not abusing their discretion and are acting in the best interest of their clients and, ultimately, the consumers," he said.

Alleged abuse of discretion is an issue confronting PBMs, which are accused by many pharmacists and some consumer groups of switching drugs only for financial gain and without regard to patient welfare. The accusations are incorrect and legislation to control PBMs is ill advised, claims Phil Blando, VP for public affairs of the Pharmaceutical Care Management Association, a PBM lobbying organization in Washington, D.C. "Laws like the Maine law have the unintended consequence of driving up the price of drugs by trying to control the ability of PBMs to negotiate the best possible price for consumers," he argued.

PBMs play a powerful role in drug distribution. The three largest PBMs—Medco Health Solutions, AdvancePCS, and Express Scripts—collectively managed nearly half of the $132 billion prescription market in 2001 and all have business ties to large pharmaceutical companies.

Medco Health Solutions in Franklin Lakes, N.J., which managed 21% of Rxs filled in 2001, is a subsidiary of pharmaceutical company Merck & Co. (Merck is expected to divest Medco later this year, but Merck officials have said the PBM will continue to promote Merck products.) AdvancePCS in Irving, Texas, with 15% of the 2001 market, owns a subsidiary that conducts trials for large pharmaceutical companies and gives vouchers to doctors for about 35 brand drugs. Express Scripts in St. Louis, with 11% of the 2001 market, recently bought a company that distributes to doctors free samples of brand drugs and literature for large pharmaceutical companies.

The PBMs have been accused by pharmacist and consumer organizations in several class action suits of pocketing large profits by acting as middlemen for some brand and generic manufacturers and keeping rebate profits rather than passing savings to their clients. In March, a suit filed in State Superior Court in Los Angeles by the American Federation of

State, County & Municipal Employees, which represents 1.3 million public employees nationwide, and the Boston consumer group Prescription Access Litigation alleged unfair market practices by the three big PBMs, and a fourth, Caremark Rx in Birmingham, Ala. The plaintiffs claim secret deals between the PBMs and drugmakers have forced consumers and public employees to pay exorbitant prices for Rx drugs.

"PBMs have been keeping their clients in the dark," commented Robert Morrissette, past president and spokesman for the Maine Pharmacy Association in South Portland. "Some have been switching consumers to more expensive drugs for their own profit." A separate new Maine law requires R.Ph.s to disclose to consumers in writing the retail cost of a drug. Morrissette said that the law, which his organization believes may not be effective, is intended to encourage consumer awareness of the high cost of branded medications.

The Maine PBM law is quite specific in governing PBM conduct. It spells out their fiduciary duties, for example, prohibiting third-party contractual relationships inconsistent with the best interest of PBM clients. It requires the disclosure of any financial terms between a PBM and a manufacturer and requires the agreement of prescribers before a PBM may switch an Rx drug to be dispensed to a consumer. Under the law, PBM profits based on the volume of drugs sold or as a result of substitution of drugs must be passed to consumers. Violations of the law are violations of the Maine Unfair Trade Practices Act, with fines of up to $10,000 per incident.

"PBMs have not been acting in the best interest of those hiring them, and one important part of the law is that they may be sued by private citizens in Maine," said Rector. "We believe this legislation is a very big deal for how PBMs will be forced to behave in the future." About 20 states are considering similar legislation, he added.

Martin Sipkoff

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 22 MRSA c. 603, sub-c. 4 is enacted to read:

SUBCHAPTER 4

PRESCRIPTION DRUG PRACTICES

§2699. Prescription drug practices

Pharmacy benefits managers shall and contracts for pharmacy benefits management must comply with the requirements of this section.

1. Definitions. As used in this chapter, unless the context otherwise indicates, the following terms have the following meanings.

A. "Covered entity" means a nonprofit hospital or medical service organization, insurer, health coverage plan or health maintenance organization licensed pursuant to Title 24 or 24-A; a health program administered by the department or the State in the capacity of provider of health coverage; or an employer, labor union or other group of persons organized in the State that provides health coverage to covered individuals who are employed or reside in the State. "Covered entity" does not include a health plan that provides coverage only for accidental injury, specified disease, hospital indemnity, Medicare supplement, disability income or other long-term care.

B. "Covered individual" means a member, participant, enrollee, contract holder or policy holder or beneficiary of a covered entity who is provided health coverage by the covered entity. "Covered individual" includes a dependent or other person provided health coverage through a policy, contract or plan for a covered individual.

C. "ERISA" means the Employee Retirement Income Security Act of 1974, 29 United States Code, Sections 1001 to 1461 (1988).

D. "Generic drug" means a chemically equivalent copy of a brand-name drug with an expired patent.

E. "Labeler" means an entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and that has a

labeler code from the federal Food and Drug Administration under 21 Code of Federal Regulations, 270.20 (1999).

F. "Pharmacy benefits management" means the procurement of prescription drugs at a negotiated rate for dispensation within this State to covered individuals, the administration or management of prescription drug benefits provided by a covered entity for the benefit of covered individuals or any of the following services provided with regard to the administration of pharmacy benefits:

(1) Mail service pharmacy;

(2) Claims processing, retail network management and payment of claims to pharmacies for prescription drugs dispensed to covered individuals;

(3) Clinical management formulary development and management services;

(4) Rebate contracting and administration;

(5) Certain patient compliance, therapeutic intervention and generic substitution programs; and

(6) Disease management programs.

G. "Pharmacy benefits manager" means an entity that performs pharmacy benefits management. "Pharmacy benefits manager" includes a person or entity acting for a pharmacy benefits manager in a contractual or employment relationship in the performance of pharmacy benefits management for a covered entity and includes mail service pharmacy.

2. Required practices. A pharmacy benefits manager owes a fiduciary duty to a covered entity and covered individuals and shall discharge that duty in accordance with the provisions of ERISA, state and federal law and this section.

A. A pharmacy benefits manager shall perform its duties with care, skill, prudence and diligence and in accordance with the standards of conduct applicable to a fiduciary in an enterprise of a like character and with like aims.

B. A pharmacy benefits manager shall discharge its duties with respect to the covered entity and covered individuals solely in the interests of the covered individuals and for the primary purpose of providing benefits to covered individuals and defraying reasonable expenses of administering health plans.

C. A pharmacy benefits manager shall notify the covered

entity in writing of any activity, policy or practice of the pharmacy benefits manager that directly or indirectly presents any conflict of interest with the duties imposed by this subsection.

D. A pharmacy benefits manager shall provide to a covered entity all financial and utilization information requested by the covered entity relating to the provision of benefits to covered individuals through that covered entity and all financial and utilization information relating to services to that covered entity. A pharmacy benefits manager providing information under this paragraph may designate that material as confidential. Information designated as confidential by a pharmacy benefits manager and provided to a covered entity under this paragraph may not be disclosed to any person without the consent of the pharmacy benefits manager, except that disclosure may be made in a court filing under the Maine Unfair Trade Practices Act or when authorized by that Act or ordered by a court of this State for good cause shown.

E. With regard to the dispensation of a substitute prescription drug for a prescribed drug to a covered individual the following provisions apply.

(1) The pharmacy benefits manager may substitute a lower-priced generic drug for a higher-priced prescribed drug.

(2) The pharmacy benefits manager may not substitute a higher-priced generic drug for a lower-priced prescribed drug.

(3) The pharmacy benefits manager shall consult with the prescribing health professional or that person's authorized representative and shall:

(a) Disclose the costs of both drugs to the covered individual and the covered entity and any benefit or payment directly or indirectly accruing to the pharmacy benefits manager as a result of the substitution; and

(b) Obtain the approval of the prescribing health professional or that person's authorized representative for the substitution.

(4) The pharmacy benefits manager shall transfer in full to the covered entity or covered individuals any benefit or payment received in any form by the pharmacy

benefits manager as a result of the prescription drug substitution.

F. A pharmacy benefits manager that derives any payment or benefit for the dispensation of prescription drugs within the State based on volume of sales for certain prescription drugs or classes or brands of drugs within the State shall pass that payment or benefit on in full to the covered entity or covered individuals.

G. A pharmacy benefits manager shall disclose to the covered entity all financial terms and arrangements for remuneration of any kind that apply between the pharmacy benefits manager and any prescription drug manufacturer or labeler, including, without limitation, formulary management and drug-switch programs, educational support, claims processing and pharmacy network fees that are charged from retail pharmacies and data sales fees.

3. Prohibition. A pharmacy benefits manager may not in a contract with a covered entity or a prescription drug manufacturer or labeler accept or agree to an obligation that is inconsistent with the fiduciary duties imposed by subsection 2, ERISA or other state or federal law.

4. Waiver prohibited. Any agreement to waive the provisions of this section is against public policy and void.

5. Enforcement. A violation of this section is a violation of the Maine Unfair Trade Practices Act. Compliance with this section may be enforced through private action or action by the Attorney General.

A. A covered entity, covered individual or other person injured as a result of a violation of this section is eligible to bring a private action as a person pursuant to the Unfair Trade Practices Act.

B. An action by the Attorney General pursuant to this subsection is subject to the provisions of this paragraph and the Maine Unfair Trade Practices Act. Each violation of this section is a civil violation for which the Attorney General may obtain, in addition to other remedies, injunctive relief and a fine in an amount not to exceed $10,000 per violation, plus the costs of suit, including necessary and reasonable investigative costs, reasonable expert fees and reasonable attorney's fees.

SUMMARY

This bill specifies the fiduciary duties of pharmacy benefits managers and the obligation to serve the covered entities with whom they contract and the covered individuals provided health care benefits by the covered entities. The bill prohibits contractual terms that are inconsistent with the pharmacy benefits manager's fiduciary duties. The bill requires payment to a pharmacy benefits manager based on volume of certain drugs or as a result of substitution of drugs to be passed on to the covered entity or covered individuals. The bill requires disclosure of financial terms that apply between a pharmacy benefits manager and a manufacturer or labeler. The bill requires consultation with and agreement of the prescribing health professional or a representative of that professional before a pharmacy benefits manager may switch a prescription drug to be dispensed to a covered individual. The bill prohibits agreements to waive provisions of the law. Violations of the law are violations of the Maine Unfair Trade Practices Act and are enforceable by private action or the Attorney General.

Attachment D

California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GRAY DAVIS, GOVERNOR

LICENSING COMMITTEE
Meeting Summary

DATE: June 24, 2003

TIME: 9:00 a.m. – 11:30 a.m.

LOCATION: Hilton Burbank Airport & Convention Center
2500 Hollywood Way
Burbank, CA

BOARD MEMBERS Clarence Hiura, Pharm.D., Chair
Don Gubbins, Jr., Pharm.D.
John Tilley, R.Ph. (absent)

STAFF PRESENT: Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
Dennis Ming, Supervising Inspector
Paul Riches, Legislative Analyst

Call to Order

Committee Chair Clarence Hiura called the meeting to order at 9:00 a.m. He commended and thanked Dr. Fong for the excellent job he did as chair of the Licensing Committee last year.

Update on the Security Breach and Halt of the Administration of the Foreign Pharmacy Graduate Equivalency Examination (FPGEE)

Ms. Harris reported that Business and Professions Code section 4200(a)(2)(B) requires an applicant who graduated from a foreign pharmacy school to receive a grade satisfactory to the board on an examination designed to measure the equivalency of foreign pharmacy education with that of domestic graduates.

To meet this requirement, the board relies on the FPGEE developed and administered by the National Association of Boards of Pharmacy (NABP).

As a result of the security breach last November, administration of the Foreign Pharmacy Graduate Equivalency Examination (FPGEE) was suspended until a new test was developed and the investigation was completed. The new FGPEE test has been developed and was administered for the first time June 21, 2003, to approximately 2,100 candidates, The new test is not computer based but was given in 4 cities nationwide, including one location in California. NABP anticipates results will be released by the end of August. Over 500 applicants took the examination in California.

There is no set date for any subsequent administrations, but NAPB anticipates the next administration to be in late 2003 or early 2004.

As reported at the last licensing committee meeting, NABP identified 15 individuals implicated to Internet postings which may have caused or contributed to the compromise. As such the scores of those candidates were invalidated. None of the individuals listed were licensees or had pending applications with the board.

Update on the Joint Legislative Sunset Review Process Regarding the California Pharmacist Licensure Examination (SB 361)

Executive Officer Harris reported that the provisions regarding the use of the national examination in California are in SB 361. This bill passed the Senate and is scheduled for a policy hearing in the Assembly Business and Professions Committee on July 1, 2002.

Competency Committee Report on the June 2003 California Pharmacist Licensure Examination

Ms. Herold reported that the board administered the pharmacist licensure examination on June 17 and 18, 2003, at the San Jose Convention and Cultural Facilities. While 1,336 applicants were scheduled to take the examination, 1,284 actually took the exam.

Grading for this exam will be conducted in Sacramento on July 16 and 17, 2003. Board member graders are needed for this administration. Examination results will be released approximately September 1, 2003. The pass rate information will be available at the October 2003 board meeting.

Implementation on the Injectable Sterile Compounding Program for Pharmacies

Ms. Harris reported that on July 1, 2003, any California pharmacy that compounds sterile injectable drug products must be licensed by the board as a compounding pharmacy unless the pharmacy is accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or the Accreditation Commission on Healthcare (ACHC).

Additionally any nonresident pharmacy that ships injectable sterile compounded products into California that is not licensed as a hospital, home health agency or skilled nursing facility and

has a current accreditation from JCAHO or ACHC must obtain a nonresident sterile compounding license from the board.

When licensure is required, part of the application process requires that the board must inspect the pharmacy. For nonresident pharmacies, the board is required to obtain a copy of the inspection report from the state pharmacy licensing agency or accreditation agency.

For the prior four months, board staff have been implementing this program. Application forms have been developed, programming for licensing records performed, training of staff provided in processing applications and condition inspections and information sessions with the profession conducted. It as been a team effort, but Supervising Inspector Dennis Ming has been instrumental in establishing the program and Suelynn Yee is processing the applications.

Applications are on the board's Web site for downloading. A self-assessment form has been developed so that pharmacies can review what elements inspectors will check during inspections. There have been a number of questions asked of diverse board staff regarding compliance and the process.

The board has also sent a letter to all state boards of pharmacy, advising them of California's requirements. It was suggested to send this information to the already licensed nonresident pharmacies.

To assure that the board inspects all sites possible before July 1, all inspectors have been assigned these inspections as a priority assignment. It was reported that as of June 23, 2003, the board had received 103 applications.

Of the 103 applications, inspectors completed 76 inspections (75%) with the remainder to be completed before June 27, 2003. Of the 76 inspections completed, 59 pharmacy sites (78%) have been approved for licensure and are compliance with CCR section 1751 (including 4 non-resident applications). Nineteen out of 76 applications (25%) were placed on hold pending corrections to come into compliance with CCR 1751. Four (4) applications were found to be accredited by JCAHO and their applications were withdrawn.

Summary of inspector activities and highlights:

- All inspectors completed a one-day training session on conducting sterile compounding inspections.
- The supervising inspector for the program completed inspection assignments with each inspector to monitor uniformity and consistency in conducting the sterile compounding inspections.
- All inspectors have been assigned sterile compounding inspections throughout the state and these inspections were made a priority.
- Inspectors have been provided a standard format for preparing sterile compounding inspection reports.

- A compliance/non-compliance checklist was developed based upon CCR 1751 and used by inspectors to evaluate the pharmacies compliance with the regulation and is available on the board's web site for the licensee's own self assessment.
- A FAQ section on sterile compounding was developed and is on the board's web site.
- Applications for the sterile compounding license have been statewide as far north as Eureka and south to San Diego.
- Northern California applications have centered in the Bay area and Sacramento.
- Southern California applications have centered primarily in Los Angeles and Orange counties with a few in Riverside and San Diego.
- Approximately 10 pharmacies have purchased a commercially available policy and procedure for sterile compounding. These versions have been found unacceptable due to the generic characteristic of the manual. Pharmacies who have submitted "canned" policies and procedures have been contacted with suggestions for revision to make the document specific for their operation. The author of the manual was contacted and advised of the issues.
- The following areas of partial or non-compliance discovered during the sterile compounding inspections have resulted in withholding the issuance of sterile compounding licenses until corrections have been documented: incomplete policies and procedure manuals, lack or incomplete cleaning logs, lack or incomplete equipment calibration logs (pumps, balances, sterilizers, incubators, refrigerators etc), lack or incomplete personnel training/competency documentation, lack or incomplete patient records (some items are difficult for community pharmacies to obtain), presence of porous ceiling tiles over the preparation area (regulation requires non-porous ceiling tiles), lack or incomplete process validation documentation, and lack or incomplete end-product testing for sterility and quantitative analysis. One pharmacy was found to use expired drugs to compound injectable medications (a violation was issued).
- Follow-up telephone calls were made to the PIC one week after the inspection to remind them to submit the requested information. The licensees have been receptive to the corrections and guidance provided during and after the inspections. The pharmacies have complied in a timely manner with providing the requested documents and/or revisions, which has resulted in a relative high number of approved applications for sterile compounding licenses.

It is anticipated that the board will receive a large number of applications during the last week of June. It will not be possible to inspect all of the late applications prior to July 1st and will require a sustained effort by the inspectors after this time period to complete the inspection portion of the licensing process.

Ms. Harris reported that the board staff specifically Supervising Inspector Dennis Ming and the inspectors have taken extraordinary efforts to ensure that pharmacies are licensed by July 1, and patient care is not interrupted.

As determined by the board at its October 2002 meeting, the existing regulations for compounding parenterals is the standard the board is enforcing with respect to licensure. Meanwhile, the board is promulgating additional regulations to deal with requirements for

compounding injectables from nonsterile ingredients. At the April 2003 meeting, changes to this regulation were adopted and released for 15 days of comment. The responses were due June 19th. These new requirements will take effect in January 2005, if the regulation is approved.

Request for Comments Regarding Program Requirements for Interns

Ms. Harris stated that one of the Licensing Committee's strategic objectives has been to review the requirements for the Intern Program. Because of other priorities, this committee has not had the opportunity to perform such a review.

The purpose of this agenda item is to initiate the review by soliciting comments on how the intern program should be updated and streamlined operationally. About 10 years ago, to assist the intern and preceptor in complying with the program requirements, the board developed its Intern/Preceptor Manual, which is available to on the board's website. The regulations governing interns are found in CCR 1728(c).

No comments were received in advance of the meeting; however, it was recommended that the internship should include experience obtained under protocol with physicians as allowed by Business and Professions Code section 4052. It was recommended that the committee contact the 6 schools of pharmacy and invite them to the next meeting to discuss this issue and the concern raised at the previous meeting regarding the gap between pharmacy school curriculum and the California pharmacist licensure examination

Invitation from ACPE to Comment on Pharmacy Technician Training and Education

ACPE has initiated a profession-wide dialog concerning the possible development of national standards and an accreditation process for pharmacy technician education and training. ACPE is the national agency for the accreditation of professional degree programs in pharmacy and providers of continuing pharmaceutical education.

The decision on whether or not to proceed with the development of national standards will be decided at ACPE's meeting in January 2004. If the decision is to establish a national standard, then ACPE anticipates that the process, from initiation to implementation will take about three years.

ACPE has invited organizations and invidividuals to submit written comments by October 31, 2003, that should be taken into consideration during this discussion. It was suggested that the board submit written comment to advise ACPE of California's education and training requirements for registration and the "pharmacy technician trainee" designee that allows practical training for the technician.

Request from the UC Davis Veterinary Medical Teaching Hospital (VMTH) for a Specialized Pharmacy Permit

Pharmacist Gale Moniz and Hospital Administrator Paul Brentson for VMTH appeared before the Licensing Committee to discuss the complexity and need for a specialized permit from the board. Prior to the opening of the VMTH as an academic fourth year clinical training facility for veterinary medical students in the School of Veterinary Medicine at UC Davis, veterinary medicine was modest, and veterinary practices were small in nature (typically a single veterinarian practice). Veterinarians ordered, managed, and dispensed their own drugs.

The VMTH, opened in 1970, was the first to consider the importance of drug management, and to incorporate this unique educational emphasis into the program by hiring a pharmacist, and centralizing the pharmacy function. Even though the functions performed at the VMTH pharmacy parallel many of those found in human healthcare settings, the emphasis is quite different. The veterinary drugs are used in the clinic (a combination of a veterinary clinic and a full service animal hospital) or are dispensed for home or farm administration to the animal patient.

The VMTH is an academic veterinary clinical training facility as well as a very large, complex veterinary practice. The standard of practice in Veterinary Medicine, as described in the Veterinary Practice Act, is the provision of drugs to a client by the veterinarian, through their practice, subsequent to a veterinarian-client-patient relationship being established.

By 1988, it was recognized that the VMTH had evolved into a very diverse and complex practice. It was also apparent that the centralized pharmacy function was recognized to be extremely important relative to (1) consistency of pharmaceutical practice, (2) having the most current pharmaceutical information available to its clients (by way of the veterinarians), (3) improving the students' education relative to the most current pharmacy practice and regulations, and (4) having the ability to order the appropriate drugs for such a complex practice quickly and efficiently. These factors led VMTH management to the conclusion that the pharmacy activity could best be managed under licensure through the Board of Pharmacy, rather than under the auspices of the individual veterinarians and Veterinary Practice Act.

At that time, the board determined that the closest fit for licensure was a drug room permit. This is a permit that is issued to hospitals that have less than 100 beds.

Subsequent to an inspection last year, it was determined by the board that this permit was not the appropriate licensure, and the only option was for licensure as a community pharmacy, which does not fit the needs of the VMTH. The other issue is that VMTH uses many human drugs that are not available through veterinary drug wholesalers and human drug wholesalers are making business decisions not to sell the drugs to VMTH even though pharmacy law does not preclude them from doing so. Veterinarians are defined as "prescibers" in pharmacy law.

Various options were discussed. An option was suggested that a "specialized" clinic permit be designed that would require a consultant pharmacist oversight over the drugs and distribution at the VMTH. It would allow for a common stock and provide a means for the VMTH to obtain a DEA permit. This option would require legislation.

The committee directed staff to work with VMTH to draft language for a specialized clinic permit and agreed to recommend to the board support of this specialized clinic permit.

Request from the Community Health Accreditation Program (CHAP) for Approval that Pharmacies Accredited by its Organzation be Exempt from Licensure pursuant to Business and Professions Code section 4127.1(d)

Business and Professions Code section 4127.1(d) requires pharmacies that compound sterile injectable drug products to obtain a special pharmacy license from the board. In order to obtain such a license, the pharmacy must first be inspected by the board and found in compliance with board standards for sterile compounding. The bill exempts pharmacies that are accredited by the Joint Commission on the Accreditation of Healthcare Organizations or other accreditation agencies approved by the board from the license requirements. Exempted pharmacies still must comply with board regulations regarding sterile injectable compounding, but do not have to obtain a separate license. At the last meeting, the board approved Accreditation Commission on Healthcare (ACHC) as an accreditation agency.

The Community Health Care Accreditation Program (CHAP) is also requesting approval as an accreditation agency as authorized under current law. CHAPS is a national non-profit accreditation organization established in 1965 to accreditate community-based health care organizations. CHAP currently accredits 35 pharmacies located in 14 states; currently there are 3 California pharmacies that are CHAP accredited and two have applied for licensure.

At its last meeting, the board recognized the importance of the 8 factors as key considerations as it works establishing a standard for analyzing accreditation applications. They are:

1. Periodic inspection – The accrediting entity must subject the pharmacy to site inspection and re-accreditation at least every three years.
2. Documented accreditation standards – The standards for granting accreditation and scoring guidelines for those standards must reflect both applicable California law and sound professional practice as established by nationally recognized professional or standard setting organizations.
3. Evaluation of surveyor's qualifications – The surveyors employed to perform site inspections must have demonstrated qualifications to evaluate the professional practices subject to accreditation.
4. Acceptance by major California payors – Recognition of the accrediting agency by major California payors (e.g., HMOs, PPOs, PBGH, CalPERS).
5. Unannounced inspection of California accredited sites – The board must conduct unannounced inspections of two or more accredited sites and find those sites in satisfactory compliance with California law and good professional practice.
6. Board access to accreditor's report on individual pharmacies.
7. Length of time the accrediting agency has been operating.
8. Ability to accredit out-of-state pharmacies. Non-resident pharmacies are eligible for licensure under the sterile compounding statutes and accreditation should be equally available to both resident and non-resident pharmacies.

The Licensing Committee discussed the accreditation process with representatives from CHAP. Supervising Inspector Dennis Ming reported that he has inspected a CHAP accredited pharmacy and found it to be in compliance. The committee recommended that the board approve CHAP as an accreditation agency contingent on the outcome of the next inspection and submission of additional paperwork, which is a comparison of standards between CHAP and JCAHO.

Review of Strategic Objectives for 2003/04

The Licensing Committee reviewed the objectives and made some technical corrections. The committee discussed exploring special educational requirements for the pharmacists in charge (PIC). Concern was expressed that many newly licensed pharmacists are not taught the skills and knowledge required to be a PIC. Even experience pharmacists are not always aware of the expectations and responsibilities expected of the PIC.

Adjournment

Committee Chair Clarence Hiura adjourned the meeting at 11:30 a.m.

Attachment E

BOARD OF PHARMACY SITE LICENSING STATISTICS - FISCAL YEAR 2002/03

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
APPLICATIONS													
Received													
Pharmacy	36	50	35	40	26	33	21	30	47	51	21	42	432
Clinics	8	13	13	7	8	9	9	4	13	22	18	32	156
Hospitals	3	5	4	1	2	0	8	0	6	0	3	4	36
Nonresident Pharmacy	3	6	8	6	3	3	5	3	5	6	6	8	62
Licensed Correctional Facility	0	0	0	1	0	0	0	0	0	0	0	0	1
Hypodermic Needles and Syringes	2	1	5	15	1	1	2	1	2	3	4	2	39
Out of State Distributor	11	8	10	3	6	6	8	5	5	11	5	11	89
Wholesalers	13	7	4	7	11	6	4	11	6	20	6	10	105
Veterinary Food-Animal Drug Retailer	0	0	0	0	0	0	0	0	0	0	0	0	0
Exemptees	37	53	39	53	37	40	64	66	68	30	46	62	595
Issued													
Pharmacy	48	39	35	36	29	37	33	23	33	58	20	39	430
Clinics	19	7	8	4	5	11	12	11	8	7	4	16	112
Hospital	8	0	4	2	2	0	7	2	5	2	2	1	35
Nonresident Pharmacy	3	7	1	4	2	5	3	10	1	3	5	2	46
Licensed Correctional Facility	0	0	0	0	0	0	0	0	0	0	0	0	0
Hypodermic Needles and Syringes	0	1	0	5	11	1	5	0	2	0	1	4	30
Out of State Distributor	7	2	2	8	5	1	4	11	10	11	5	6	72
Wholesalers	16	6	1	10	5	4	4	2	6	9	1	2	66
Veterinary Food-animal Drug Retailer	1	0	0	0	0	0	0	0	0	0	0	0	1
Exemptees	33	33	26	37	18	18	50	37	50	26	44	42	414

BOARD OF PHARMACY SITE LICENSING STATISTICS - FISCAL YEAR 2002/03

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Pending													
Pharmacy	70	77	76	80	77	68	56	62	73	65	66	69	69
Clinics	30	33	34	37	40	37	34	26	24	36	50	66	66
Hospital	35	39	39	38	38	38	39	37	38	36	37	40	40
Nonresident Pharmacy	28	26	35	37	38	35	37	29	31	33	34	40	40
Licensed Correctional Facility	1	1	0	1	1	1	1	1	1	1	1	1	1
Hypodermic Needles and Syringes	3	2	7	16	5	5	1	2	1	4	7	0	0
Out of State Distributor	30	36	44	39	39	43	47	48	37	37	11	11	11
Wholesalers	33	34	37	34	39	40	39	48	44	53	9	12	12
Veterinary Food-Animal Drug Retailer	0	0	0	0	0	0	0	0	0	0	0	0	0
Exemptees	54	67	76	87	101	112	109	105	119	123	0	0	0
Change of Pharmacist-in-Charge													
Received	259	191	191	230	204	150	198	157	177	167	147	194	2265
Processed	260	120	192	181	168	226	199	186	229	170	142	75	2148
Pending	119	190	189	238	274	198	243	214	162	159	164	283	283
Change of Permits													
Received	49	51	48	45	19	70	28	67	28	60	74	46	585
Processed	95	46	46	40	34	46	20	44	38	18	64	74	565
Pending	163	168	170	175	160	184	192	215	205	247	257	229	229
Discontinuance of Business													
Received	27	23	14	20	15	16	21	26	16	19	7	16	220
Processed	16	0	1	0	29	0	33	1	32	16	0	0	128
Pending	49	72	85	105	*46	62	50	75	59	62	69	85	85

BOARD OF PHARMACY SITE LICENSING STATISTICS - FISCAL YEAR 2002/03

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Renewals Received													
Pharmacy/Hospitals	887	824	197	496	291	313	426	619	818	568	78		5517
Clinics	66	49	46	47	33	45	76	50	57	61	48		578
Nonresident Pharmacy	21	9	10	18	7	13	11	12	10	20	7		138
Hypodermic Needles and Syringes	39	15	15	19	28	26	25	11	16	15	14		223
Out of State Distributor	35	16	24	22	15	15	31	22	22	17	18		237
Wholesalers	57	28	26	37	20	36	46	31	39	35	26		381
Veterinary Food-Animal Drug Retailer	5	0	0	0	0	0	0	0	4	1	0		10
Exemptees	181	67	83	119	95	105	133	123	139	107	69		1221

*hand count

Attachment F

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GRAY DAVIS, GOVERNOR

NO ACTION
REPORT ONLY

COMPETENCY COMMITEE REPORT TO THE BOARD MEMBERS FROM THE LICENSING COMMITTEE CLARENCE HIURA, CHAIR JULY 7, 2003

1. Report on the June 2003 Examination

On June 17 and 18, 2003, the board administered its June 2003 pharmacist licensure examination at the San Jose Convention and Cultural Facilities. Of the 1336 candidates scheduled for the examination, 1284 candidates took the examination.

Grading for this exam will be conducted in Sacramento on July 16 and 17, 2003. Examination results are scheduled to be released approximately September 1, 2003. Passing rate information will be available at the October 2003 board meeting.

2. Competency Committee Annual Meeting

The Competency Committee will meet on August 7 and 8, 2003, for its annual meeting. The purpose of the annual meeting is to focus on the long-term goals of the committee and to review the examination process with the intent of making improvements, and to work on questions for the item bank.

3. Report on the January 2004 Examination

On January 13 and 14, 2004, the board will administer its January 2004 pharmacist licensure examination at the Hyatt Regency San Francisco Airport Hotel.

Staff Contact: Debbie Anderson
(916) 445-5014, ext. 4007

Attachment G

Quarterly Report

2002/03
July 2003
Final Report

Licensing

Goal

Ensure the professional qualifications of pharmacists and establish the minimum standards for board-licensed facilities.

Implementation Responsibility

Licensing Committee and Staff

Strategic Objectives		Timeline
1. Meet performance expectations for processing license applications to note deficiencies within 7 days of receipt, process deficiency documents within 3 days of receipt and issue licenses once deficiencies are corrected within 3 days.		Ongoing
10/02	*Licensing data reported at October Board Meeting – average time to process provided in Sunset Report.*	
11/02	*Promoted from within a licensing technician to process applications for new compounding licensure program. Leaves a clerical vacancy in the facility licensure program.*	
12/02	*Program analyst for facility licensure program retired and until position filled, duties were reorganized.*	
1/03	*Licensing data reported at January Board Meeting.*	
4/03	*Licensing data reported at April Board Meeting.*	
7/03	*Licensing data reported at July Board Meeting.*	
2. Review the Intern program.		July 2003
7/02	*Board approved the sponsorship of legislation to authorize the supervision of two interns by a pharmacist.*	

Strategic Objectives		Timeline
10/02	*Review of Intern Program scheduled for March 03 committee meeting.*	
3/03	*Review of intern program rescheduled for future committee meeting when schools of pharmacy representatives attend and initial discussions can begin.*	
6/03	*Requested comments for modifications to Intern Program. No written comments were received. Will request comments from the 6 schools of pharmacy.*	
3.	Review the Technician Registration Program that will include the use of the Pharmacy Technician Certification Board (PTCB), supervision ratio of all ancillary personnel, and expanded duties that a PTCB registered pharmacy technician may perform.	July 2003
9/02	*Presentation on PTCB certification process.*	
9/02	*Recommended as a qualifier for technician registration: PTCB certification, associate degree in pharmacy technology only, eliminate "clerk typist" experience and clarify training requirements.*	
9/02	*Recommended pharmacies to supervise 4 ancillary personnel in any combination - ancillary personnel defined as pharmacist intern, pharmacy technician and pharmacy technician trainee.*	
10/02	*Presentation on the PTCB examination and process to Board at its public meeting.*	
10/02	*Board approved recommended legislation and regulation changes to the technician registration program.*	
10/02	*Board approved recommended changes to the ancillary ratio and supervision flexibility.*	
11/02	*Responded to issues raised by the Joint Legislative Sunset Review Committee (JLSRC) regarding technician program and ratios.*	
11/02	*Referred the board-approved pharmacy technician and ancillary ratios changes to the Legislation/Regulation Committee.*	
4/03	*JLSRC supported board's proposal to revise registration and program requirement (SB 361).*	

Strategic Objectives		Timeline
5/03	*SB 361 passed the Senate.*	
7/03	*SB 361 scheduled for hearing in Assembly B&P Committee.*	
4. Increase the ratio on the number of clerk-typists that a pharmacist can supervise at his or her discretion.		July 2003
7/02	*Board approved regulation change to eliminate clerk-typist ratio.*	
8/02	*Proposed regulation change to eliminate clerk typist ratio pending with Legislation/Regulation Committee.*	
7/03	*Proposed regulation change awaiting notice.*	
5. Develop language and pursue a regulation change to allow the central fill of medication orders for inpatient hospital pharmacies.		July 2003
9/02	*Discussed proposed language. Requested interested parties to submit modifications to the proposed regulation language.*	
10/02	*Board approved proposed regulation change.*	
11/02	*Referred board-approved proposed regulation for central fill for hospital pharmacies to the Legislation/Regulation Committee.*	
4/03	*Proposed regulation awaiting notice.*	
6. Explore the feasibility of offering the California pharmacist licensure examination more than twice a year.		July 2003
9/02	*Discussed feasibility and compared costs of offering the California exam more than twice a year.*	
9/02	*Governor signed AB 2165 which requires the Joint Legislative Sunset Review Committee to review the state's shortage of pharmacists and a course of action to alleviate the shortage including review of the licensure examination.*	
11/02	*Provided data and costs on options regarding the pharmacist licensure exam to the Joint Legislative Sunset Review Committee.*	

Strategic Objectives		Timeline
4/03	*JLSRC and Department of Consumer Affairs recommend that the board adopt the national exam (SB 361).*	
5/03	*SB 361 passed the Senate.*	
7/03	*SB 361 scheduled for hearing in the Assembly B&P Committee.*	
7. Assist applicants preparing for the California pharmacists licensure examination by developing (or fostering the development of) educational programs and information on how to prepare for the pharmacist exam and by requesting that outside agencies (schools of pharmacy and private educational organizations) develop exam workshops that prepare applicants for the California Pharmacist Exam.		July 2003
12/02	*Additional practice "essay" and multiple-choice questions were added to board's web site.*	
7/03	*Licensing Committee will invite the deans from the 6 California pharmacy schools to its September meeting to discuss examination issues.*	
8. Develop statutory language to grant the Board of Pharmacy the authority to grant waivers for innovative, technological and other practices to enhance the practice of pharmacy and patient care that would have oversight by an independent reviewing body during the study.		July 2003
9. Explore the feasibility and need to regulate Pharmacy Benefit Managers (PBMs).		July 2003
12/02	*Discussed the need to regulate PBMs and had a representative from the Department of Managed Care to provide information on their oversight responsibility.*	
12/02	*Recommended that the PBM discussion continue at the January Board Meeting.*	
1/04	*Board created an ad hoc Committee on PBM regulation comprised of 3 public board members.*	
3/03	*Held first Ad Hoc PBM regulation meeting.*	
6/03	*Held second Ad Hoc PBM regulation meeting. Speakers presented on the development of formularies.*	

Ongoing Objectives

10. Issue professional and occupational licenses to those individuals and firms that meet minimum requirements:

    - Pharmacists
    - Intern pharmacists
    - Pharmacy technicians
    - Foreign educated pharmacists (evaluations)
    - Pharmacies
    - Non-resident pharmacies
    - Wholesaler drug facilities
    - Veterinary food animal drug retailers
    - Exemptees (the non-pharmacists who may operate sites other than pharmacies)
    - Out-of-state distributors
    - Clinics
    - Hypodermic needle and syringe distributors

    9/02 *Licensed over 415 new pharmacists within two weeks of results being released, approximately 90% issued within 24 hours of receiving fee.*

    9/02 *Revised intern processing requirements for foreign graduates who do not have a social security number.*

    10/02 *Reported licensing data for FY 02/03 at October Board Meeting.*

    11/02 *Issued 747 technician registrations in 4 weeks due to redirection of resources to process applications and decision not to respond to telephone inquiries for status of applications. Sent out over 500 letters on applications that have been deficient since July 1.*

    12/02 *Reported that there was a breach of security with the FPGEE examination that resulted in the invalidation of scores. Impact was not known. FPGEE exam is suspended until a new exam is developed by June 2003.*

    1/03 *Reported licensing data for FY 02/03 at January Board Meeting.*

    1/03 *Board administers license exam to 675 candidates.*

    3/03 *Issued 283 out of 385 pharmacist licenses from the January exam.*

    3/03 *During 1st quarter of 2003, the board issued 1432 technician registrations.*

    4/03 *Reported licensing data for FY 02/03 at April Board Meeting.*

    4/03 *Received 912 pharmacist applications and over ½ have been processed.*

    4/03 *Developed criteria to evaluate accreditation agencies for approval.*

4/03 *Began implementation process for pharmacies that compound injectable sterile drugs – developed applications, a self-assessment form, a FAQ and trained inspectors on the inspection process.*

4/03 *Approved ACHC as an accreditation agency.*

6/03 *Received 103 applications and inspected 76 sites for licensure by July 1.*

6/03 *Scheduled 1,336 applicants for the June examination.*

6/03 *Reported that the FPGEE was administered to 2,100 applicants.*

7/03 *Reported licensing data for FY 02/03 at the July Board Meeting.*

7/03 *Received approximately 6,453 technician applications and issued 6077 permits. This is a 43% increase of the permits issued last year.*

11. Assure that pharmacists fulfill continuing education requirements via diversity of available programs and through compliance audits.

9/02 *Held informational hearing on proposed regulation to allow pharmacists to obtain CE credit from CE programs approved by other health regulatory boards.*

10/02 *Board approved granting CE to pharmacist for attending board meetings.*

11/02 *Regulation change to accept approved CE from other licensing boards is pending review by OAL.*

12/02 *Enforcement Committee recommended that 6 hours of CE be granted to pharmacists for attending board meetings.*

1/03 *Board agreed to grant 6 hours of CE to pharmacists for attending board meetings.*

4/03 *Implemented CE policy for attending April Board Meeting.*

5/03 *Regulation change to accept approved CE from other licensing boards is pending review by OAL.*

12. Evaluate the license application process to prevent enforcement problems and reduce application review time; implement improvements to the processing of applications consistent with protection of public health and safety; determine distribution of resources among program components.

8/02 *Reviewed accuracy of information for licensees on web site and updated information.*

9/02 *Suspended the mailing of applications due to fiscal constraints – available to download from web site.*

9/02 *Developed procedures to issue "temporary" permits to facilities during an application investigation and when there is a change of ownership.*

9/02 *Continued evaluation of workload on pharmacy technician desk – other staff redirected to assist with processing.*

11/02 *Developed procedures to address incomplete applications for changes in the PIC, DOBs and change of permits and referral to the Enforcement Unit for a citation and fine.*

12/02 *Evaluated workload on site processing desks to redistribute and prioritize assignments due to 2 vacancies in the unit.*

12/02 *Developed informational sheets for licensed facilities on what to do when changes occur to their operation.*

13. Cashier all application and renewal fees promptly.

9/02 *Redirected and trained new staff to temporarily assist with renewal cashiering.*

14. Provide accurate verification of licensure and other public record information requested regarding board licenses.

9/02 *Received 213 public records request and 1 Subpoena.*

10/02 *Web site hits were 545,474, of these, 171,814 were for web site look-up.*

12/02 *Received 225 public records request and 4 subpoenas.*

1/03 *Web site hits from Oct.- December were 530,253. Total web site hits for January 2002 – December 2002 were 1.9 million.*

3/03 *Received 200 public records requests and 1 subpoena.*

4/03 *Web site hits from Jan. – March 03 were 661,342. Total web site hits from July 1 – March 30 were 1,678,925.*

7/03 *Web site hits from April – June 03 were 751.018.*

7/03 *Web site hits for 02/03 were 2,463,370.*

7/03 *For FY 02/03 received 1,390 public record requests and 11 subpoenas.*

15. Assure the public safety by approving waivers of licensing requirements pursuant to Business and Professions Code Sections 4118, 4137, 4197, and California Code of Regulations Section 1717.

8/02 *Noticed regulation change to CCR 1717(e) to allow the delivery of medications to non-pharmacy sites when a patient is not present. Noticed without regulation hearing.*

9/02 *Request from Cedars Sinai and Long Beach Medical Centers to extend technician check technician study for another two years to pursue legislation to allow the practice. Recommended that it be extended for one year only.*

10/02 *Proposed regulation change to CCR 1717(e) to board for vote.*

10/02 *Board adopted regulation change to CCR 1717(e).*

10/02 *Request for waiver of CCR 1717(e) from Ramona Pharmacy.*

10/02 *Board granted waiver of CCR 1717(e) to Romona Pharmacy pending supervising inspector review.*

12/02 *Adopted amendment to CCR 1717(e) to Office of Administrative Law for approval.*

3/03 *Regulation change to CCR 1717(e) became effective. Waiver is no longer necessary.*

16. Review and make recommendations to revise the Pharmacy Law and the board's regulations to reflect current practice.

10/02 *Recommended changes to the pharmacy technician registration requirements and other modifications to clarify law.*

10/02 *Recommended new regulation to allow automated central fill for hospital pharmacies.*

10/02 *Board approved changes to the pharmacy technician program and central fill for hospital pharmacies – Referred to Legislation/Regulation Committee.*

17. Continuously review and develop written exams to ensure they fairly and effectively test the knowledge, skills and abilities of importance to the practice of pharmacy in California.

8/02 *Held retreat to plan future examinations.*

10/02 *Report from Competency Committee on the pharmacist licensure examination.*

10/02 *Will request waiver to extend existing contract for examination consultant for one-year because of review of California examination by the Joint Legislative Sunset Review Committee.*

10/02 *Waiver to extend existing examination consultant for one year was denied. Initiated process to secure new examination consultant contract.*

1/03 *Released RFP for exam consultant.*

1/03 *Report from Competency Committee on the pharmacist licensure examination.*

4/03 *Report from Competency Committee on the pharmacist licensure examination.*

18. Evaluate the distribution channels of dangerous drugs and dangerous devices from manufacturing to patients to ensure the maintenance of drug efficacy, integrity, and accountability.

7/02 *Met with the Veterinary Board regarding the distribution of dangerous drugs for animal use in California and via the Internet. Discussed need to clarify pharmacy law.*

9/02	*Noticed proposed regulations for pharmacies that compound sterile products – Regulation hearing scheduled for October Board Meeting.*
9/02	*DCA convened meeting with board, Medical Board and interested parties to discuss prescriber dispensing.*
9/02	*Considered proposed regulation change for central fill at hospital pharmacies.*
10/02	*Held regulation hearing to establish standards for pharmacies that compound medications. Regulations were tabled for discussion at the December Licensing Committee meeting. Will license pharmacies that compound injectable sterile drug products based on current regulations.*
11/02	*Board agreed to joint task force with Medical Board on prescriber dispensing. Enforcement Committee members will participate on task force.*
12/02	*Held a public meeting and discussed proposed regulations for pharmacies that compound injectable sterile medications.*
12/02	*Agreed to meet with the Department of Health's State Food and Drug on compounding and manufacturing issues.*
12/02	*Held second informational hearing on the standards for pharmacies that compound injectable sterile medications.*
1/03	*DCA convened a meeting with Veterinary Board to discuss the distribution of dangerous drugs for animal use in CA and via the Internet. Discussed the need to clarify existing law.*
2/03	*Legislation was introduced to clarify the dispensing of dangerous drugs for animal use in CA and via the Internet to clarify and strengthen the law (SB 175). Amendments were suggested and identified facility licensure for CA veterinarian school.*
3/03	*Discussed with DHS – State Food and Drug the goal of future meetings to address compounding and manufacturing. A task force will be formed upon the conclusion of the PBM ad hoc committee.*
4/03	*Scheduled hearing on proposed amendments to sterile compounding regulation.*
4/03	*Board adopted the sterile compounding regulation with some minor modifications.*
4/03	*Board took a support position on SB 175.*